

PATENT COOPERATION TREATY

PCM
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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rules 59.3(e) and 61.1(b), first sentence
and Administrative Instructions, Section 601(a))

To:
RICHARD C. WOODBRIDGE
WOODBRIDGE & ASSOCIATES, P.C.
P.O. BOX 592
PRINCETON, NJ 08540

Date of mailing
(day/month/year)

16 OCT 2001

Applicant's or agent's file reference 370-117.1.1 3704-117.1.1.1 WO		IMPORTANT NOTIFICATION	
International application No. PCT/US01/047586	International filing date (day/month/year) 14 FEB 01	Priority date (day/month/year) 12 FEB 98	
Applicant CASE MEDICAL INC.			

1. The applicant is hereby notified that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

18 Sept. 01

2. That date of receipt is:

- ☒ the date of receipt of the demand by this Authority (Rule 61.1(b)).
☐ the date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).
☐ the date at which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/E...), received the required corrections.

3. ☐ **ATTENTION:** If the date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the demand does (do) not have the effect of postponing the entry into the national phase until 30 months (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 30 months from the priority date (or later in some Offices) (Article 22). For details, see the PCT Guide II.

- ☐ (If applicable) This notification confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3. Yes, a copy of this notification has been sent to the International Bureau.

Name and mailing address: Assistant Commissioner Box PCT Washington, D.C. 200 Facsimile No. 703-305-3639	Authorized officer Jeryl McDowell
Form PCT/IPEA/402 (I)	Telephone No. 703-305-3639

OCT 22 2001

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF WITHDRAWAL OF PRIORITY CLAIM

Administrative Instructions, Section 415(a) and (b))

From the INTERNATIONAL BUREAU

To:

WOODBIDGE, Richard, C.
Woodbridge & Associates, P.C.
P.O. Box 592
Princeton, NJ 08542
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 06 July 2001 (06.07.01)	
Applicant's or agent's file reference 3704-117.1.1.1 WO	IMPORTANT NOTIFICATION
International application No. PCT/US01/04786	International filing date (day/month/year) 14 February 2001 (14.02.01)
Applicant CASE MEDICAL INC.	

1. The applicant is hereby notified that **the priority claim made in the international application has been withdrawn** in accordance with a notice of withdrawal received from the applicant on:

05 July 2001 (05.07.01)

The attention of the applicant is drawn to the fact that the withdrawal of the priority claim will result in the re-calculation of time limits which have not already expired (see Rule 90bis.3(d)).

2. ☒ In the case where **multiple priorities** have been claimed, the above action relates to the following priority claim(s):

US	26 August 1998 (26.08.98)	PCT/US/98/17671
US	12 February 1998 (12.02.98)	09/023,055

3. A copy of this notification has been sent to the receiving Office and to:

- ☒ the International Searching Authority (*where the international search report has not yet been issued*)
☒ the designated Offices (*which have already been notified of the receipt of the record copy*)
☐ the International Preliminary Examining Authority

JUL 16 2001

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer L. Homero Hernandez Telephone No. (41-22) 338.83.38
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PATENT COOPERATION TREATY

From the RECEIVING OFFICE

To:
RICHARD C. WOODBRIDGE
WOODBRIDGE & ASSOCIATES, P.C.
P.O. BOX 582
PRINCETON, NJ 08542

PCT

NOTIFICATION RELATING TO PRIORITY CLAIM

(PCT Rules 26bis.1 and 26bis.2 and
Administrative Instructions, Sections 302 and 314)

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CPIR

Date of mailing (day/month/year)	06 SEP 01
Applicant's or agent's file reference 3704-117.1.1 • WO	IMPORTANT NOTIFICATION
International application No. PCT/US01/04786	International filing date (day/month/year) 14 FEB 01
Applicant CASE MEDICAL INC.	

The applicant is hereby notified of the following in respect of the priority claim(s) made in the international application.

1. ☒ **Correction of priority claim.** In accordance with the applicant's notice received on : 16 April 2001
 the following priority claim has been corrected to read as follows:
60/184,299
☐ even though the indication of the number of the earlier application is missing.
☐ even though the following indication in the priority claim is not the same as the corresponding indication appearing in the priority document.
2. ☐ **Addition of priority claim.** In accordance with the applicant's notice received on :
 the following priority claim has been added:
☐ even though the indication of the number of the earlier application is missing.
☐ even though the following indication in the priority claim is not the same as the corresponding indication appearing in the priority document.
3. ☒ **As a result of the correction and/or addition of (a) priority claim(s) under items 1 and/or 2, the (earliest) priority date is:**
23 February 2000
4. ☐ **The priority claim (see also item 5, below, if applicable) is considered not to have been made because:**
☐ the applicant failed to respond to the invitation under Rule 26bis.2(a) (Form PCT/RO/110) within the prescribed time limit.
☐ the applicant's notice was received after the expiration of the prescribed time limit under Rule 26bis.1(a).
☐ the applicant's notice failed to correct the priority claim so as to comply with the requirements of Rule 4.10.
 The applicant may, before the technical preparations for international publication have been completed and subject to the payment of a fee, request the International Bureau to publish, together with the international application, information concerning the priority claim. See Rule 26bis.2(c) and the *PCT Applicant's Guide*, Volume I, Annex B2(1B).
5. ☐ **In case where multiple priorities have been claimed, the above item(s) relate to the following priority claim(s):**
6. ☒ **A copy of this notification has been sent to the International Bureau and**
☒ **to the International Searching Authority**

Name and mailing address of the receiving Office Assistant Commissioner for Patent Box PCT Washington, D.C. 20231 Attn:RO/US Facsimile No. 703-305-3230	Authorized officer Jeryl McDowell <i>JMM</i> Telephone No. 703-305-3639
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Form PCT/RO/111 (July 1998)



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 14 JUN 2002

WIPO

PCT

Applicant's or agent's file reference 3704-117.1.1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US01/04786	International filing date (day/month/year) 14 February 2001 (14.02.2001)	Priority date (day/month/year) 23 Feb. 2000
International Patent Classification (IPC) or national classification and IPC IPC(7): A61L 2/14 and US Cl.: 422/292		
Applicant CASE MEDICAL, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand ✓ 18 September 2001 (18.09.2001)	Date of completion of this report 09 May 2002 (09.05.2002)
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer <i>Sean Conley</i> Telephone No. 703-308-0661

I. Basis of the report1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-20 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages NONE, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages 21-24, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the drawings:
pages 1-15, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US01/04786**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1-17</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-17</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-17</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-17 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the features claimed in the amendment filed under PCT Article 34. The amended claims overcome the prior art cited in the international search report.

More specifically, the prior art does not teach or fairly suggest an aluminum sterilization container comprising an oxide film coating covering the aluminum lid of the container and also does not teach an aluminum bottom with a thickness ranging from 0.2 mils to 0.3 mils.

Furthermore, the prior art does not teach or fairly suggest an aluminum container wherein the metal lid and metal bottom are electrically insulated from each other as stated in claim 10 of the present invention.

The closest prior art to the claimed invention belongs to Spence (U.S. Pat. 4,783,321) and Stone et al. (U.S. Pat. 5,732,821).

Spence teaches a sterilization container system for sterilizing medical instruments. The container has a lid secured to a base. Also, the container has multiple vent holes in the top and bottom for receiving a gas sterilant. The container further comprises a filter sealed over the vents. However, the invention does not teach an oxide film covering the material of the container and also does not teach a top and bottom that are electrically insulated from each other.

Stone et al. discloses a container for sterilizing medical devices. The container has a top and bottom, both of which have vent holes for passing a sterilant through the container. The material selected for the container is aluminum. However, this invention also does not teach an oxide film covering the aluminum lid of the container and also does not teach or disclose electrically insulating the top and bottom from each other.

Therefore, the claims as submitted under PCT Article 34 are considered to be novel and inventive.

CORRECTED
VERSION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

10/070621

REC'D 06 DEC 2002

WIPO PCT

Applicant's or agent's file reference 3704-117.1.1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US01/04786	International filing date (day/month/year) 14 February 2001 (14.02.2001)	Priority date (day/month/year) 26 August 1998 (26.08.1998)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61L 2/14 and US Cl.: 422/292		
Applicant INC., CASE MEDICAL		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 14 February 2001 (14.02.2001)	Date of completion of this report 09 May 2002 (09.05.2002)
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Sean Conley <i>for</i> Telephone No. 703-308-0661

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US01/04786

I. Basis of the report**1. With regard to the elements of the international application:***☐ the international application as originally filed.☒ the description:

pages 1-20 _____ as originally filed

pages NONE _____, filed with the demandpages NONE _____, filed with the letter of _____.☒ the claims:pages NONE _____, as originally filedpages NONE _____, as amended (together with any statement) under Article 19

pages 21-23 _____, filed with the demand

pages NONE _____, filed with the letter of _____.☒ the drawings:

pages 1-15 _____, as originally filed

pages NONE _____, filed with the demandpages NONE _____, filed with the letter of _____.☐ the sequence listing part of the description:pages NONE _____, as originally filedpages NONE _____, filed with the demandpages NONE _____, filed with the letter of _____.**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☐ The amendments have resulted in the cancellation of:**☐ the description, pages NONE☐ the claims, Nos. NONE☐ the drawings, sheets/fig NONE**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).****

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US01/04786**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)

Claims 1-17 YESClaims NONE NO

Inventive Step (IS)

Claims NONE YESClaims NONE NO

Industrial Applicability (IA)

Claims 1-17 YESClaims NONE NO**2. CITATIONS AND EXPLANATIONS**

Claims 1-17 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the features claimed in the amendment filed under PCT Article 34. The amended claims overcome the prior art cited in the international search report.

More specifically, the prior art does not teach or fairly suggest an aluminum sterilization container comprising an oxide film coating covering the aluminum lid of the container and also does not teach an aluminum bottom with a thickness ranging from 0.2 mils to 0.3 mils.

Furthermore, the prior art does not teach or fairly suggest an aluminum container wherein the metal lid and metal bottom are electrically insulated from each other as stated in claim 10 of the present invention.

The closest prior art to the claimed invention belongs to Spence (U.S. Pat. 4,783,321) and Stone et al. (U.S. Pat. 5,732,821).

Spence teaches a sterilization container system for sterilizing medical instruments. The container has a lid secured to a base. Also, the container has multiple vent holes in the top and bottom for receiving a gas sterilant. The container further comprises a filter sealed over the vents. However, the invention does not teach an oxide film covering the material of the container and also does not teach a top and bottom that are electrically insulated from each other.

Stone et al. discloses a container for sterilizing medical devices. The container has a top and bottom, both of which have vent holes for passing a sterilant through the container. The material selected for the container is aluminum. However, this invention also does not teach an oxide film covering the aluminum lid of the container and also does not teach or disclose electrically insulating the top and bottom from each other.

Therefore, the claims as submitted under PCT Article 34 are considered to be novel and inventive.

----- NEW CITATIONS -----

WE CLAIM:

1. A metal sterilization container (100, 200) used for sterilizing instruments placed therein and surrounded by a gas plasma sterilizing medium, said container (100, 200) comprising:

5 an aluminum lid (102, 226) having a first set of vent holes (114, 202 and 204) therein;

an aluminum bottom (104) attachable to said lid (102, 226), said bottom (104) having sidewalls (106) and a base (108);

a second set of vent holes (116) located in said base (108) of said bottom
10 (104);

a filter medium (124, 206, 212), permeable to the flow of gas plasma but inhibiting dust and other airborne particles and microorganisms, associated with each of said sets of vent holes (114, 116, 202 and 204); and

an oxide film covering said aluminum lid (102, 226) and said aluminum
15 bottom (104) of a thickness of from 0.2 mils (0.0002 inches) to 0.3 mils (0.0003 inches).

wherein the gas plasma sterilizing medium passes through said first set of vent holes (114, 202 and 204) and filter medium, around the inside of said container (100, 200) and exits through said second (116) set of vent holes and filter medium.

20 2. The container of claim 1 wherein the aluminum is 6061-TG.

3. The container of claim 1 further comprising a third set of vent holes (118) located in said base (108) of said bottom (104).

4. The container of claim 3 wherein said first set of vent holes (114, 202 and 204) and said second (116) and said third (118) set of vent holes are offset in a
25 predetermined direction relative to each other whereby the gas plasma sterilizing medium may pass through said first set of vent holes (114, 202 and 204) through said container (100, 200) and be forced to move in a direction different than said predetermined direction to pass through said second (116) and said third (118) set of

vent holes thereby creating a turbulent flow of said gas plasma within said container (100, 200), and

wherein said oxide film covering is of a thickness no less than 0.2 mils (0.0002 inches).

5 5. The container of claim 4 wherein said oxide film covering is of a thickness no greater than 0.3 mils (0.0003 inches).

6. The container of claim 5 wherein said aluminum is 6061 T-6.

7. The container of claim 6 wherein said gas plasma has an electric field effect.

10 8.. The apparatus of claim 1 further comprising:
a fourth set of vent holes (204) located in said lid (226), and
wherein said lid (226) has a minor dimension center line (226) and said first (202) and fourth (204) set of vent holes are located on opposite sides of said minor dimension center line (226).

15 9. The apparatus of claim 1 wherein said gas plasma has an electric field effect.

20 10. A system for sterilizing sterilizable items in a container with a gas plasma, said system comprising:

means for introducing a gas plasma (160, 162);

20 an aluminum lid (102, 226) having a first set of vent holes (114, 202 and 204) located therein;

an aluminum bottom (104) attachable to said lid (102, 226), said bottom (104) further including a base (108) having a center line (120) through its minor planar dimension;

25 a second (116) and third (118) set of vent holes located on opposite sides of said minor dimension center line (120) of said base (108);

PAT/US 01/04786
HQ/US 18 SEP 2001

filter means (124, 206), permeable to the flow of gas plasma but inhibiting dust and other airborne particles and microorganisms, located adjacent to said sets (114, 202, 204, 116, 118) of vent holes,

5 wherein said gas plasma passes through said first set (114, 202 and 204) of vent holes and said filter means (124, 206), comes into contact with said sterilizable items, and exits through said second (116) and third (118) sets of vent holes and said filter means (124, 206), and

wherein said metal lid (102, 226) and said metal bottom (104) are electrically insulated from one another.

10 11. The system of claim 10 further comprising:

a fourth set of vent holes (204) located in said lid (226), and,

wherein said lid (226) has a minor dimension center line (226) and said first (202) and fourth (204) set of vent holes are located on opposite sides of said minor dimension center line (226).

15 12. The system of claim 11 wherein said gas plasma has an electric field effect.

13. The system of claim 12 wherein said aluminum lid (102, 226) and said aluminum bottom (104) are electrically insulated from one another.

20 14. The system of claim 13 wherein said insulation is formed by said oxide film covering said aluminum lid (102, 226) and said aluminum bottom (104).

15. The system according to claim 14 wherein said oxide film covering is of a thickness no less than 0.2 mils (0.0002 inches).

16. The system according to claim 15 wherein said oxide film covering is of a thickness no greater than 0.3 mils (0.0003 inches).

25 17. The system according to Claim 16 wherein said aluminum is 6061-TG.

AMENDED SHEET

The demand must be filed directly with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line

IPEA/ US

PCT

DEMAND

CHAPTER II

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA

Date of receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION

Applicant's or agent's file reference

3704-117.1.1.1WO

International application No.

PCT/US01/04786

International filing date (day/month/year)

14 February 2001 (14/02/01)

(Earliest) Priority date (day/month/year)

23 February 2000 (23/02/00)

Title of invention

FILTERED GAS PLASMA STERILIZATION CONTAINER WITH IMPROVED CIRCULATION

Box No. II APPLICANT(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Case Medical Inc.
65 Railroad Avenue
Ridgefield, NJ 07657
UNITED STATES

Telephone No.

201-313-1999

Facsimile No.

201-313-9090

Teleprinter No.

Applicant's registration No. with the Office

State (that is, country) of nationality:

us

State (that is, country) of residence:

us

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

State (that is, country) of nationality:

State (that is, country) of residence:

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

State (that is, country) of nationality:

State (that is, country) of residence:

☐

Further applicants are indicated on a continuation sheet.

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is ☒ agent ☐ common representative
 and ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.
☐ is hereby appointed and any earlier appointment of (an) agent(s) /common representative is hereby revoked.
☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official
 The address must include postal code and name of country.)*

Woodbridge, Richard C.
 Woodbridge & Associates, P.C.
 P.O. Box 592
 Princeton, NJ 08542
 United States

Telephone No.

609-924-3773

Facsimile No.

609-924-1811

Teleprinter No.

Agent's registration No. with the Office
 26,423

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION**Statement concerning amendments:***

1. The applicant wishes the international preliminary examination to start on the basis of:

☒ the international application as originally filed.

the description ☒ as originally filed
☐ as amended under Article 34

the claims ☐ as originally filed
☐ as amended under Article 19 (together with any accompanying statement)
☒ as amended under Article 34

the drawings ☐ as originally filed
☐ as amended under Article 34

2. ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. ☐ The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: ENGLISH

☒ which is the language in which the international application was filed.
☐ which is the language of a translation furnished for the purposes of international search.
☐ which is the language of publication of the international application.
☐ which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby elects all eligible States *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

excluding the following States which the applicant wishes not to elect:

B x No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | |
|--------------------------------------------------------------------------|---|--------|
| 1. translation of international application | : | sheets |
| 2. amendments under Article 34 | : | sheets |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | sheets |
| 4. copy (or, where required, translation) of statement under Article 19 | : | sheets |
| 5. letter | : | sheets |
| 6. other (<i>specify</i>) | : | sheets |

For International Preliminary Examining Authority use only

- | received | not received |
|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> |

The demand is also accompanied by the item(s) marked below:

- | | |
|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> fee calculation sheet | 5. <input type="checkbox"/> statement explaining lack of signature |
| 2. <input type="checkbox"/> original separate power of attorney | 6. <input type="checkbox"/> sequence listing in computer readable form |
| 3. <input type="checkbox"/> original general power of attorney | 7. <input checked="" type="checkbox"/> other (<i>specify</i>): Acknowledgement Post Card |
| 4. <input type="checkbox"/> copy of general power of attorney; reference number, if any: | |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).


Richard C. Woodbridge, Agent

Woodbridge & Associates, P.C.
P.O. Box 592
Princeton, NJ 08542

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply.

☐ The applicant has been informed accordingly.

4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.

5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	<p style="text-align: center;">FOR FURTHER ACTION</p>	<p>see Notification of Transmittal of International Search Report (Form PCT/ISA/210) as well as, where applicable, item 5 below.</p>	
International application No. PCT/US01/04786		International filing date (<i>day/month/year</i>) 14 February 2001 (14.02.2001)	(Earliest) Priority Date (<i>day/month/year</i>) 23 February 2000 (23.02.2000)
Applicant Case Medical Inc.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 13. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.



It is also accompanied by a copy of each prior art document cited in this report

1. **Basis of the Report**

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. 1A

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☒ because his figure better characterizes the invention.

☐ None of the figures

Form PCT/ISA/210 (first sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/4786

Box I Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 4 of first sheet)

This International Searching Authority ☒ multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, the international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest☐
☐

The additional search fees were accompanied by the applicant's protest

No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet(1)) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/USC/04786

Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

INTERNATIONAL SEARCH REPORT

International Application No.

P/S01/01736

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61L 2/14

US CL : 422 292

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 422/292, 267, 300; 215/305; 206/439; 220/324, 254, 297, 293, 913

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
USPTO APS "metal sterilizing container", "plasma gas", "oxide film", "aluminum sterilization container"**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,731,821 (STONE et al) 31 March 1998 (31.03.1998), column 6, lines 40-45.	1,3,4,8,10,12,14,20
Y	US 5,521,755 (DEEDS) 11 June 1996 (11.06.1996), column 2, lines 16-33; Fig. 1; Fig. 2.	1,4,12,14
Y	US 4,781,321 (SPENCE) 08 november 1988 (08.11.1988), column 1, lines 15-20, column 2, lines 1-16.	1,4,5,10,12,14
Y	US 5,321,489 (NICHOLS et al) 28 June 1994 (28.06.1994), claim 1.	1,4,10,12,14
Y	US 4,711,025 (NICHOLS) 29 December 1987 (29.12.1987), column 2, lines 22-45.	1,4,10,12,14
Y	US 5,651,693 (CAMBELL et al) 22 July 1997 (22.07.1997), column 4, lines 50-57.	9,11,15
Y	Australia 202,334 (KRACKLAUER et al) 28 May 1954 (28.05.1954).	1,12
A	US 5,371,787 (RITTER) 13 December 1994 (13.12.1994), claim 1.	1,4,10,12,14
A	US 5,621,970 (BASILE et al) 13 May 1997 (13.05.1997), Abstract.	1,4,10,12,14

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex

* Special categories of cited documents:	"T"
"A" document defining the general state of the art which is not considered to be of particular relevance	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken as prior art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more of the other cited documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

02 April 2001 (02.04.2001)

Date of mailing of the international search report

Name and mailing address of the ISA/I/S

Commissioner of Patents and Trademarks

Box PCT

Washington, D. C. 20231

Facsimile No. (703)305-3230

Authorized officer

Sean Conley

Telephone No. 703-308-0661

CLERK COPY

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only	
PCT/US 01/04786	
International Application No.	
(14-02-01)	14 FEB 2001
International Filing Date	
PCT INTERNATIONAL APPLICATION RO/US	
Name of receiving Office and "PCT International Application"	
Applicant's or agent's file reference (if desired) (12 characters maximum)	3704-117.1.1.1 WO

Box No. I TITLE OF INVENTION	
FILTERED GAS PLASMA STERILIZATION CONTAINER WITH IMPROVED CIRCULATION	
Box No. II APPLICANT	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
CASE MEDICAL INC. 65 Railroad Avenue Ridgefield, NJ 07657 US	<input type="checkbox"/> This person is also inventor. Telephone No. 201-313-1999 Facsimile No. 201-313-9090 Teleprinter No.
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input checked="" type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
FRIEZE, ALLAN S 45 Berkery Place Alpine, NJ 07620-0472 US	This person is: <input type="checkbox"/> applicant only <input checked="" type="checkbox"/> applicant and inventor <input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
<input checked="" type="checkbox"/> Further applicants and/or (further) inventors are indicated on a continuation sheet.	
Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: <input checked="" type="checkbox"/> agent <input type="checkbox"/> common representative	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
WOODBIDGE, RICHARD C. WOODBIDGE & ASSOCIATES, P.C. P.O. Box 592 Princeton, New Jersey 08542 US	Telephone No. 609-924-3773 Facsimile No. 609-924-1811 Teleprinter No.
<input type="checkbox"/> Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.	

Continuation of Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTOR(S)*If none of the following sub-boxes is used, this sheet is not to be included in the request.*

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

FRIEZE, MARCIA A.
45 Berkery Place
Alpine, NJ 07620-0472
US

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only
☐ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

PCT/US 01/04786

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- ☒ **AP ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
|------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> AE United Arab Emirates | <input checked="" type="checkbox"/> LR Liberia |
| <input checked="" type="checkbox"/> AL Albania | <input checked="" type="checkbox"/> LS Lesotho |
| <input checked="" type="checkbox"/> AM Armenia | <input checked="" type="checkbox"/> LT Lithuania |
| <input checked="" type="checkbox"/> AT Austria | <input checked="" type="checkbox"/> LU Luxembourg |
| <input checked="" type="checkbox"/> AU Australia | <input checked="" type="checkbox"/> LV Latvia |
| <input checked="" type="checkbox"/> AZ Azerbaijan | <input checked="" type="checkbox"/> MA Morocco |
| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina | <input checked="" type="checkbox"/> MD Republic of Moldova |
| <input checked="" type="checkbox"/> BB Barbados | <input checked="" type="checkbox"/> MG Madagascar |
| <input checked="" type="checkbox"/> BG Bulgaria | <input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input checked="" type="checkbox"/> BR Brazil | |
| <input checked="" type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> MN Mongolia |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> MW Malawi |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> CN China | <input checked="" type="checkbox"/> NO Norway |
| <input checked="" type="checkbox"/> CR Costa Rica | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> CU Cuba | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> CZ Czech Republic | <input checked="" type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> DE Germany | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> DK Denmark | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> DM Dominica | <input checked="" type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> EE Estonia | <input checked="" type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> ES Spain | <input checked="" type="checkbox"/> SG Singapore |
| <input checked="" type="checkbox"/> FI Finland | <input checked="" type="checkbox"/> SI Slovenia |
| <input checked="" type="checkbox"/> GB United Kingdom | <input checked="" type="checkbox"/> SK Slovakia |
| <input checked="" type="checkbox"/> GD Grenada | <input checked="" type="checkbox"/> SL Sierra Leone |
| <input checked="" type="checkbox"/> GE Georgia | <input checked="" type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> GH Ghana | <input checked="" type="checkbox"/> TM Turkmenistan |
| <input checked="" type="checkbox"/> GM Gambia | <input checked="" type="checkbox"/> TR Turkey |
| <input checked="" type="checkbox"/> HR Croatia | <input checked="" type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> TZ United Republic of Tanzania |
| <input checked="" type="checkbox"/> ID Indonesia | <input checked="" type="checkbox"/> UA Ukraine |
| <input checked="" type="checkbox"/> IL Israel | <input checked="" type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> IN India | <input checked="" type="checkbox"/> US United States of America |
| <input checked="" type="checkbox"/> IS Iceland | |
| <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> UZ Uzbekistan |
| <input checked="" type="checkbox"/> KE Kenya | <input checked="" type="checkbox"/> VN Viet Nam |
| <input checked="" type="checkbox"/> KG Kyrgyzstan | <input checked="" type="checkbox"/> YU Yugoslavia |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea | <input checked="" type="checkbox"/> ZA South Africa |
| | <input checked="" type="checkbox"/> ZW Zimbabwe |
| <input checked="" type="checkbox"/> KR Republic of Korea | |
| <input checked="" type="checkbox"/> KZ Kazakhstan | |
| <input checked="" type="checkbox"/> LC Saint Lucia | |
| <input checked="" type="checkbox"/> LK Sri Lanka | |

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

☐
☐

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time



RO/US 16 APR 2001

Box No. VI PRIORITY CLAIM		<input type="checkbox"/> Further priority as indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: regional Office	international application: receiving Office
item (1) February 23, 2000	60/184,299	US		
item (2) August 20, 1998	PCT/US/98/17871			
item (3) February 12, 1998	60/184,299	US		

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): 1, 2 and 3.

Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA)
(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):

ISA/ us

Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):

Date (day/month/year) Number Country (or regional Office)

Box No. VIII CHECK LIST: LANGUAGE OF FILING

This international application contains the following number of sheets:	This international application is accompanied by the item(s) marked below:
request : 4	1. <input checked="" type="checkbox"/> fee calculation sheet
description (excluding sequence listing part) : 20	2. <input checked="" type="checkbox"/> separate signed power of attorney
claims : 4	3. <input type="checkbox"/> copy of general power of attorney; reference number, if any:
abstract : 1	4. <input type="checkbox"/> statement explaining lack of signature
drawings : 15	5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s):
sequence listing part of description : _____	6. <input type="checkbox"/> translation of international application into (language):
Total number of sheets : 44	7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material
	8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form
	9. <input checked="" type="checkbox"/> other (specify): Post Card and Express Mail Cert. No. EL640249353US

Figure of the drawings which should accompany the abstract:

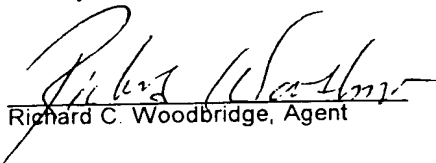
6A

Language of filing of the international application:

English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).


Richard C. Woodbridge, Agent

(14-62-51)

For receiving Office use only		2. Drawings: <input type="checkbox"/> received <input type="checkbox"/> not received
1. Date of actual receipt of the purported international application:	Rec'd PCT/PTO 11 FEB 2001	
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:		
4. Date of timely receipt of the required corrections under PCT Article 11(2):		
5. International Searching Authority (if two or more are competent): ISA/US	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.	

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

02/14/01
Jc490 U.S. PRO

2-15-01
This sheet is not part of and does not count as a sheet of the international application.

PCT

PCT
FEE CALCULATION SHEET
Annex to the Request

For receiving Office use only

PCT/US 01/04786
International application No.

(14-02-01)

14 FEB 2001

Applicant's or agent's
file reference **3704-117.1.1.1 WO**

Applicant
CASE MEDICAL INC., et al.

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE

240.00 T

2. SEARCH FEE

0.00 S

International search to be carried out by **US**

(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application contains **44** sheets.

first 30 sheets

b1

14 x **\$10.00**
remaining sheets additional amount

140.00 b2

Add amounts entered at b1 and b2 and enter total at B

140.00 B

Designation Fees

The international application contains **83** designations.

8

82.00

number of designation fees payable (maximum 8) x amount of designation fee

656.00 D

Add amounts entered at B and D and enter total at I

796.00 I

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT (if applicable)

45.00 P

5. TOTAL FEES PAYABLE

1,081.00

Add amounts entered at T, S, I and P, and enter total in the TOTAL box

TOTAL

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

☐ authorization to charge
deposit account (see below)

☐ bank draft

☐ coupons

☒ cheque

☐ cash

☐ other (specify):

☐ postal money order

☐ revenue stamps

DEPOSIT ACCOUNT AUTHORIZATION (this mode of payment may not be available at all receiving Offices)

The RO/ **US** ☐ is hereby authorized to charge the total fees indicated above to my deposit account.

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POWER OF ATTORNEY

(for an international application filed under the Patent Cooperation Treaty)

(PCT Rule 90.4)

The undersigned applicant(s) *(Names should be indicated as they appear in the request):*

CASE MEDICAL, INC.

FRIEZE, ALLAN S.

FRIEZE, MARCIA A.

hereby appoints (appoint) the following person as:



agent



common representative

Name and address

(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

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P.O. Box 592

Princeton, New Jersey 08542-0592

US

Richard C. Woodbridge - 26,423

Stuart H. Nissim - 33,541

to represent the undersigned before



all the competent International Authorities



the International Searching Authority only



the International Preliminary Examining Authority only

in connection with the international application identified below:

Title of the invention: FILTERED GAS PLASMA STERILIZATION CONTAINER WITH IMPROVED CIRCULATION

Applicant's or agent's file reference: 3704-117.1.1.1 WO

International application number (if already available):

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and to make or receive payments on behalf of the undersigned.

Signature of the applicant(s) *(where there are several applicants, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading the request or this power):*

CASE MEDICAL INC

By:

Allan S. Frieze, President

Dated:

2-3-01

Allan S. Frieze

Dated:

2-3-01

Marcia A. Frieze

Dated:

2-3-01

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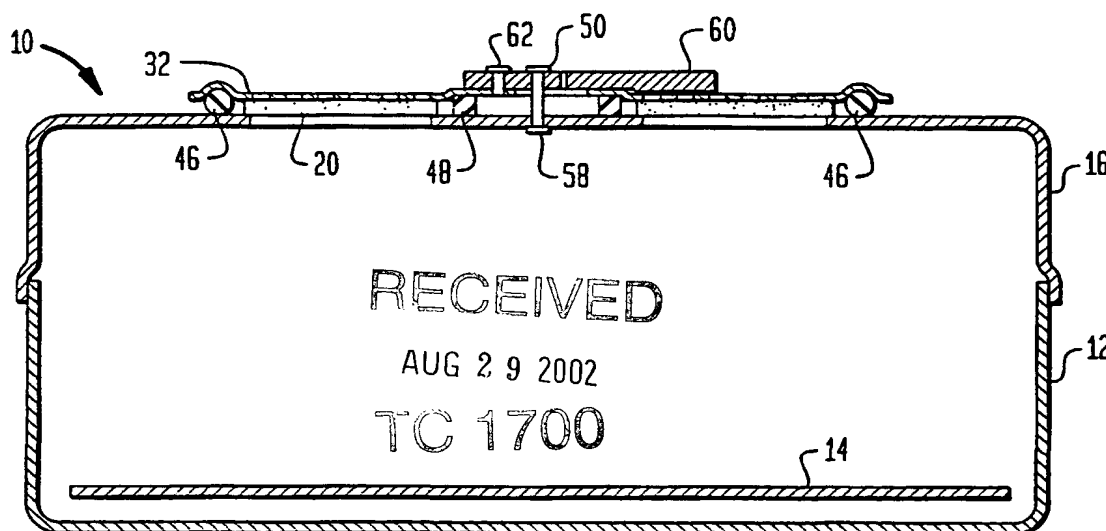
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- (51) International Patent Classification⁷: A61L 2/14 (74) Agent: WOODBRIDGE, Richard, C.; Woodbridge & Associates, P.C., P.O. Box 592, Princeton, NJ 08542 (US).
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- (71) Applicant (for all designated States except US): CASE MEDICAL INC. [US/US]; 65 Railroad Avenue, Ridgefield, NJ 07657 (US).
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- (72) Inventors; and
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(54) Title: FILTERED GAS PLASMA STERILIZATION CONTAINER WITH IMPROVED CIRCULATION



(57) Abstract: A metal sterilization container (10) comprises a pan (12) forming the bottom of the container holding a tray (14), with a cover (16) forming the top of the container, and a filter element (20). The filter (20) covers an opening in the cover (16) so that the inside of the container (10), formed when the cover is removably sealed to the pan (12), can communicate with the atmosphere surrounding the sealed container allowing gas plasma to enter and exit the container passing through the filter (20). Items to be sterilized are placed on the tray (14) and the cover (16) is attached and sealed to the pan (12). The sealed container is then placed in a gas plasma environment. The container is preferably made of aluminum with an anodic coating of 0.5 mils (0.0005 inches) or less with the pan (12) and cover (16) electrically insulated from one another via the coating.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/04786

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61L 2/14

US CL : 422/292

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 422/292, 26, 27, 300; 215/305; 206/439; 220/324, 254, 297, 293, 913

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
USPTO APS "metal sterilizing container", "plasma gas", "oxide film", "aluminum sterilization container"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,732,821 (STONE et al) 31 March 1998 (31.03.1998), column 6, lines 40-45.	1,3,4,8,10,12,14,20
Y	US 5,524,755 (DEEDS) 11 June 1996 (11.06.1996), column 2, lines 16-33; Fig. 1; Fig. 2	1,4,12,14
Y	US 4,783,321 (SPENCE) 08 november 1988 (08.11.1988), column 1, lines 15-20, column 2, lines 6-16.	1,4,5,10,12,14
Y	US 5,324,489 (NICHOLS et al) 28 June 1994 (28.06.1994), claim 1.	1,4,10,12,14
Y	US 4,716,025 (NICHOLS) 29 December 1987 (29.12.1987), column 2, lines 22-45.	1,4,10,12,14
Y	US 5,650,693 (CAMBELL et al) 22 July 1997 (22.07.1997), column 4, lines 50-57.	9,11,15
Y	Australia 202,334 (KRACKLAUER et al) 28 May 1954 (28.05.1954).	1,12
A	US 5,372,787 (RITTER) 13 December 1994 (13.12.1994), claim 1.	1,4,10,12,14
A	US 5,628,970 (BASILE et al) 13 May 1997 (13.05.1997), Abstract.	1,4,10,12,14

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	"&" document member of the same patent family

Date of the actual completion of the international search 02 April 2001 (02.04.2001)	Date of mailing of the international search report 08 JUN 2001
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FIG. 7B

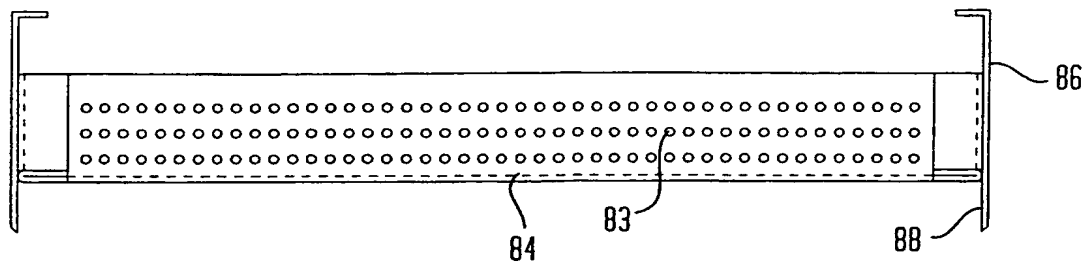


FIG. 7C

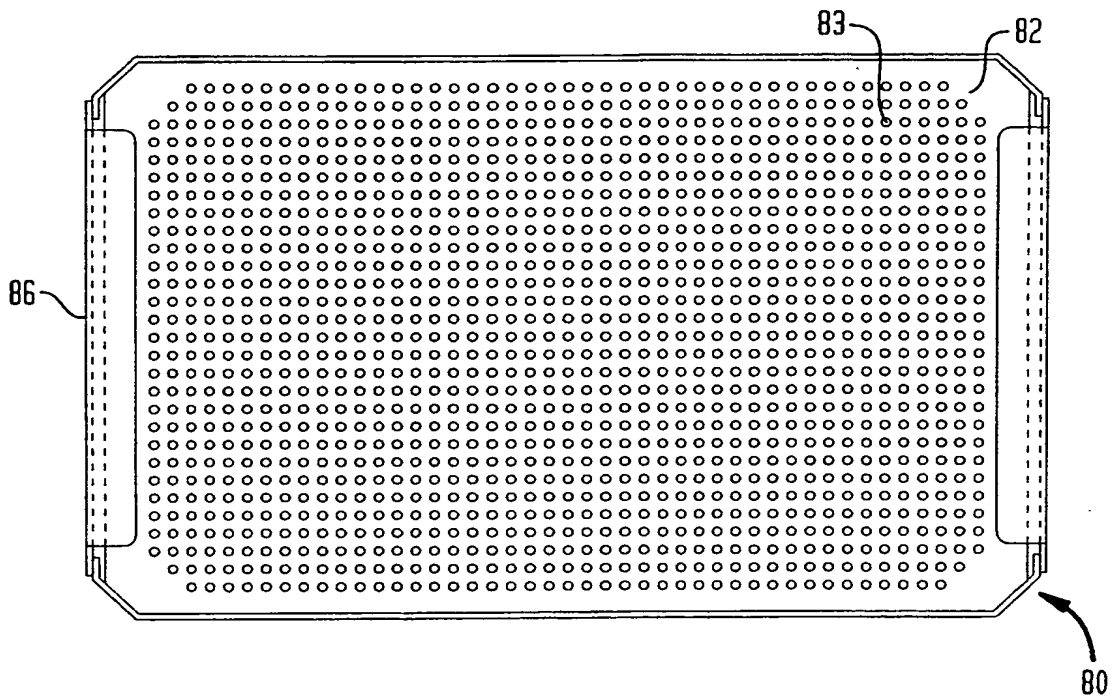
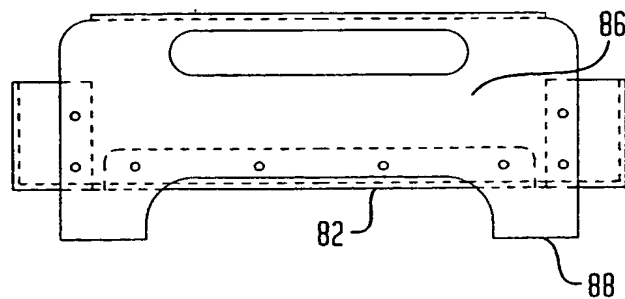


FIG. 7D



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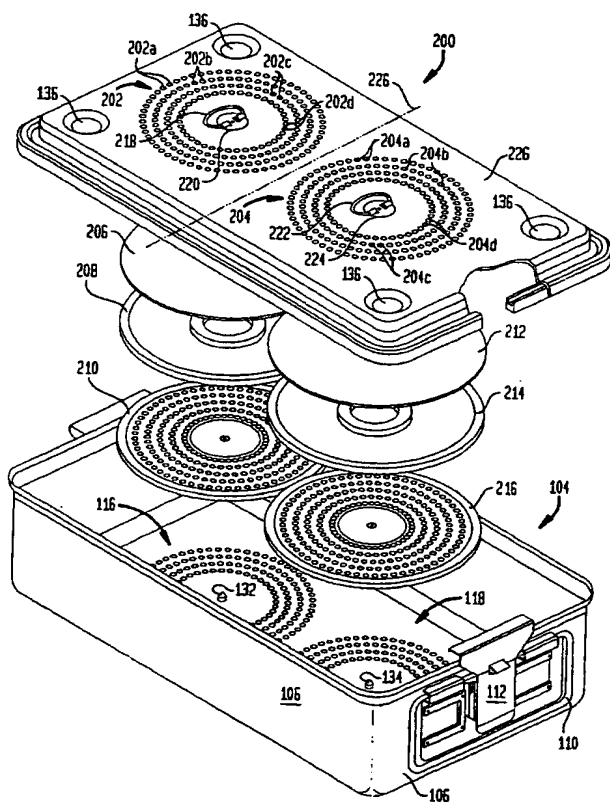
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60/184,299 23 February 2000 (23.02.2000) US
- (71) Applicant (for all designated States except US): **CASE MEDICAL INC.** [US/US]; 65 Railroad Avenue, Ridgefield, NJ 07657 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **FRIEZE, Allan, S.** [US/US]; 45 Berkery Place, Alpine, NJ 07620-0472 (US). **FRIEZE, Marcia, A.** [US/US]; 45 Berkery Place, Alpine, NJ 07620-0472 (US).
- (74) Agent: **WOODBIDGE, Richard, C.**; Woodbridge & Associates, P.C., P.O. Box 592, Princeton, NJ 08542 (US).
- (81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
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(54) Title: **FILTERED GAS PLASMA STERILIZATION CONTAINER WITH IMPROVED CIRCULATION**



(57) Abstract: A metal sterilization container (10) comprises a pan (12) forming the bottom of the container holding a tray (14), with a cover (16) forming the top of the container, and a filter element (20). The filter (20) covers an opening in the cover (16) so that the inside of the container (10), formed when the cover is removably sealed to the pan (12), can communicate with the atmosphere surrounding the sealed container allowing gas plasma to enter and exit the container passing through the filter (20). Items to be sterilized are placed on the tray (14) and the cover (16) is attached and sealed to the pan (12). The sealed container is then placed in a gas plasma environment. The container is preferably made of aluminum with an anodic coating of 0.5 mils (0.0005 inches) or less with the pan (12) and cover (16) electrically insulated from one another via the coating.

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**TITLE: FILTERED GAS PLASMA STERILIZATION
CONTAINER WITH IMPROVED CIRCULATION**

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of our co-pending U.S. application serial no. 09/023,055 filed on February 12, 1998, and a continuation-in-part of our co-pending PCT application no. PCT/US/98/17671 filed on August 26, 1998, the entire contents and substance of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates, in general, to a method for sterilizing medical instruments, in particular, to a sterilization container useful for flash sterilization and gas plasma sterilization, which includes a filter that permits maximum gas sterilant penetration and prevents microorganisms and dust from entering, and which permits for stat flash sterilization by restricting the volume, and therefore the mass, of instruments placed into the container by utilizing a basket which fits into the container.

2. Description of Related Art

Steam sterilization is a common method used for the sterilization of items, especially medical instruments by processing the items in an autoclave and exposing them to high-pressure steam. This method requires the wrapping of individual items, heating the items with steam and then waiting for a drying/cooling period. Often during surgical procedures commonly used instruments are needed on a "stat" basis, i.e., the instruments need to be quickly sterilized after use or inadvertent contamination. Under such circumstances the standard autoclave method would take too long. An alternative sterilization method, which can be used under these circumstances, is known as flash sterilization. In flash sterilization metal instruments are not wrapped but are heated

directly by the steam allowing sterilization in a reduced period of time. One drawback to the use of flash sterilization is the lack of a drying period. When the items are still moist and hot from sterilization, microorganisms and dust can contaminate the items when they are transported from the autoclave/sterilizer. Nevertheless, flash sterilization results in reduced exposure time.

Sterilization time can also be reduced by limiting the amount of instruments placed into the sterilization container. If too many instruments with too much mass are placed into the sterilization container, "stat" sterilization will not be effective. One method to restrict the amount of instruments placed into the sterilization container is to weigh the instruments. Weighing of instruments, however, can be time consuming in itself and difficult to control given the various sizes, shapes and odd surface areas of medical instruments.

One common design for containers for flash sterilization is described in U.S. Patents 5,097,865 and 4,748,003. Such containers use valves which require greater than atmospheric pressures to open the valves and allow the high-pressure steam to enter the container but are closed under normal pressure conditions. This approach has a number of disadvantages. Such containers must be opened to allow the steam to escape, thus breaking the sterile field. Even if kept sealed, these containers cannot maintain the sterile field for longer than 24 hours. Also, the high temperature, high-pressure valves needed for this method are very complex and very expensive. In addition, such containers do not provide an indication as to whether or not the valve properly functioned to allow the high pressure steam to enter the container.

In addition to flash steam sterilization the industry is beginning to use gas plasma as an alternative. One commercially available gas plasma system is sold as STERRAD® by Advanced Sterilization Products, a division of the Johnson & Johnson

Company. Gas plasma has known advantages over steam sterilization, including sterilizing at a lower temperature than required for steam sterilization, which is beneficial when sterilizing temperature-sensitive devices. However, it has been learned that frequently the sterilizing gas plasma does not reach all important surfaces on the inside of the sterilization container, especially where long tubular instruments or cables are contained. Accordingly, there are believed to be very few sterilization containers approved for use with gas plasma, especially in the mid-size range. Clearly a technique is missing in the prior art to guarantee satisfactory circulation of gas plasma within a sterilization container, especially where it is critical to reach the edges and corners of the interior of the sterilization container and to penetrate internal components such as laparoscopic guides and tubing. The present invention, however, maintains its efficacy when utilized with gas plasma as the sterilant.

SUMMARY OF THE INVENTION

Briefly described, the invention comprises a sterilization for sterilizing items, which allow for extended, sterile storage of the sterilized items. The flash sterilization method uses a sterilization container having a pan, a cover and one or more filters for preventing dust and microorganisms from entering the container and contaminating the sterilized items while still allowing gas plasma in and out of the container during the sterilization process. These containers can be used in the flash sterilization process commonly used in surgical theaters. The filter can be permanently mounted in the container or can be removable for replacement with new or different types of filters. Removable filters will allow for the retrofitting of currently used containers with the filters so that new containers do not need to be purchased to take advantage of the filtered flash sterilization method of the present invention. The filter can be removably

attached to the container, manufactured as an integral part of the container, or incorporated into a self-contained removable filter unit.

A filter is attached to the sterilization container through a filter retainer. The filter retainer has a plurality of gas plasma penetration holes which can be of various sizes and shapes allowing sufficient gas plasma to enter the container. The filter retainer also comprises one or more gaskets for maintaining a seal between the filter retainer and the sterilization container as well as a locking means for removably attaching the retainer to the container.

Another aspect of the present invention allows for instruments to be sterilized on a "stat" basis by utilizing a basket which limits the amount of instruments that can be placed into the container for sterilization. When instruments need to be sterilized on a "stat" basis, for example, because the instrument became contaminated during the surgical procedure and no other such instrument is available, the time required to sterilize the instrument can be drastically reduced by limiting the amount or volume of instruments sterilized through utilization of a size restricted basket containing the instruments which would fit into the sterilization container. This indirectly limits the total mass of instruments to be sterilized, which in turn, reduces the sterilization time.

Another alternative embodiment of the invention provides for a single set of vent holes in the center of the lid, or cover, of the container and two sets of vent holes, arranged in a circular fashion, located in the base of the pan or bottom of the container. The second and third sets of vent holes in the base are located on opposite sides of the minor axis center line of the base in such a way that they do not overlap. Gas plasma passing through the first set of vent holes in the lid is then forced to travel to the extremes of the container in order to be exhausted thereby guaranteeing that all parts of

the tray or sterilizable instruments on the inside come into contact with the gas plasma as well as the edges and corners and interior of the container.

According to yet another embodiment of the invention, a pair of vent means, comprising a first and fourth set, are located in the lid in a manner similar to the way the second and third set of vent holes are located in the base. This also helps to guarantee thorough circulation of the gas plasma within the container. These two improvements are especially suited for use with mid-size sterilizable containers that employ gas plasma as the sterilizing agent. This invention, however, enhances the efficacy of gas plasma sterilization. The first, second, third and fourth sets of vent holes are preferably each arranged in four concentric circles having the holes on their circumference. Other alternative, symmetrical patterns, like square, would also be acceptable. The keeper plate on the bottom of the container preferably includes a similar set of holes, but offset so that there can be no "striethrough" of sharp objects through the filter underneath the series of vent holes but above the keeper plate.

These and other features of the invention may be more fully understood by reference to the following drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a perspective view of the flash sterilization container invention.

Fig. 1B is a top perspective view of the flash sterilization container cover with a filter retainer.

Fig. 1C is a perspective view of the flash sterilization container invention with the top surface of the lid having a D-ring attached to it.

Fig. 2A is an exploded perspective view of the flash sterilization container filter invention.

Fig. 2B is a partial view of a cover opening configuration.

Fig. 3A is a side elevational view of the filter retainer invention.

Fig. 3B is a top plan view of the filter retainer invention with the locking means in the locked position.

Fig. 3C is a top plan view of the filter retainer invention with the locking means in the unlocked position.

Fig. 4A is a partial, side elevational view of a flash sterilization container cover with an incorporated filter.

Fig. 4B is a partial, side elevational view of a flash sterilization container and a filter cartridge.

Fig. 5A is an exploded view of an alternative embodiment of the invention especially suitable for use with gas plasma in which the base of the container includes two sets of circular vent holes located on opposite sides of the center line of the minor axis of the container.

Fig. 5B is a top plan view of the lid of the alternative embodiment illustrated in Fig. 5A.

Fig. 5C is an elevational cross-sectional view of the lid illustrated in Fig. 5B.

Fig. 5D is a partial, cross-sectional exploded view of the top, or first set, of circular vent means illustrated in a manner in which the pull ring is attached to the lid.

Fig. 5E is a detailed, cross-sectional end view of the lid of Fig. 5B illustrated in a manner in which the snap-on post attaches to the filter retainer plate.

Fig. 5F illustrates the bottom, or pan, of the gas plasma alternative embodiment illustrating how the second and third set of circular vent means are located on opposite sides of the center line of the minor axis of the bottom portion.

Fig. 6A is an exploded view of another alternative embodiment of the gas plasma container illustrating a fourth set of circular vent means located adjacent to said first set of circular vent means in the top of lid of the container.

Fig. 6B is a top plan view of the lid of the alternative embodiment illustrated in

5 Fig. 6A.

Fig. 6C is a side elevational cross-sectional view of the lid illustrated in Fig. 6B.

Fig. 6D is a partial, detail exploded view of the first set of circular vent means illustrating the manner in which the pull ring is attached to the lid.

Fig. 7A is a perspective view of the preferred embodiment of the instrument
10 limiting basket with a divider system.

Fig. 7B is a side, elevation view of the basket with handles and feet.

Fig. 7C is top plan view of the base of the basket with the divider system removed.

Fig. 7D is a side, elevation view of the basket handle and feet shown in Fig. 7A.

15 **DETAILED DESCRIPTION OF THE INVENTION**

During the course of this description like numbers will be used to identify like elements according to the different figures that illustrate the invention.

A flash sterilization container 10 is illustrated in Fig. 1. A Sterilization container 10 comprises a pan 12, which forms the bottom of the container that holds
20 and supports a conventional sterilizable tray 14, and a cover 16, which forms the top of the container. The cover is removably attached to the pan to form a hermetically sealed container. This can be accomplished by conventional means such as hinges and clamps and a sealing gasket. The cover 16 is provided with an opening 18 at its top. This opening 18 is covered with a filter 20 to allow gas plasma to enter and exit the
25 container through the opening by passing through the filter. The filter can be



removably or permanently attached to the cover. This filter is made of a material, or combination of materials, such that the filter is permeable to the flow of gas plasma but will inhibit dust or other airborne particles or microorganisms from passing through. Examples of such materials include paper, TEFLON[®], a registered trademark of E.I. Du Pont de Nemours and Co., Inc., porous stainless steel, polysulfone, and hydrophobic material, such as GOR-TEX[®], a registered trademark of W.L. Gore & Associates, and Kimguard[®], a trademark of the Kimberly-Clark Corporation. The filter is attached to the cover by means which will prevent any gas plasma, dust or other airborne particles or microorganisms from passing through the opening in the cover without passing through the filter.

The filter 20 is placed over the opening 18 in the top of the cover 16 and the filter is attached to the cover by a filter retainer 30. One embodiment of such a filter retainer is illustrated in figures 1A, 1B, 2A, 3A and 3B. The filter retainer 30 comprises a filter retainer disc 32 and a means for sealing the filter retainer disc to the cover. The filter retainer disc has an inner disc 34, a middle ring 36, and an outer ring 38. The middle ring 36 has a plurality of holes 40 to allow the flow of gas plasma through the filter retainer disc 32, through the filter 20, and through the opening 18 in the cover 16. The filter retainer can have one or more sealing means for forming a seal between the filter and the cover. The outer ring 38 has a means for forming a seal between the filter and the cover. In one embodiment the outer ring has an inverted-U shaped cross-section. A gasket 46 is placed in the inverted-U outer ring and can be made of silicone, neoprene, TEFLON[®], a registered trademark of E.I. Du Pont de Nemours and Co., Inc., or any other suitable material. Inner disc 34 may also have a sealing means if necessary, such as a gasket 48.

The preferred metal that is used for the container is the aluminum alloy 6061 with a T-6 heat treatment. This alloy (6061 T-6) is treated electrolytically in a bath containing sulfuric acid to produce a uniform anodic coating on the metal surface. The thickness of the aluminum anodizing should not exceed 0.5 mils (.0005 inches) and preferably should have a coating between 0.2 mils (.0002 inches) and 0.3 mils (.0003 inches). This is less than the normally allowed specifications which allows up to 0.7 mils (.0007 inches). Coating below 0.5 mils results in improved sterilization characteristics in the container over thicker coatings and it appears that the coatings in the range of 0.2 mils to 0.3 mils provides the best results.

All parts of the container should be anodized after all heat treatment, machining, welding, forming and perforating has been completed. The anodic coating should not be applied to assemblies which will entrap the electrolyte in joints or recesses. Assemblies, which contain non-aluminum parts such as steel, brass, or organic substances which would be attacked by pretreatment or anodizing solutions or prevent uniform formation of the anodic or prevent uniform formation of the anodic coating, shall not be anodized as an assembly unless proper protection can be provided to ensure the anodic coating meets the specification, e.g., masking of non-aluminum surfaces or electrically insulating such surfaces. It is important to keep the aluminum parts clean of all foreign substances, such as grease and welding flux and free of metals, such as steel or iron, which would accelerate corrosion of the aluminum alloy. After applying a uniform anodic coating, all parts should be completely sealed in a known manner.

A means for attaching the filter retainer to the cover is illustrated in figures 1A, 1B, 2A, 3A, and 3B. Pin 50 extends upwards from the top surface of the cover 16. Inner disc 34 of the filter retainer disc 32 has a hole 42 for accepting pin 50. Pin 50 has sufficient length to extend past the top surface of the filter retainer 30 when the filter

retainer is placed on the cover 16 allowing the hole in the inner disc 42 to engage the pin 50. Pin 50 is preferably located in the center of the opening 18 in the cover 16. To locate the pin in the proper position, the opening in the cover can be, for example, a circular opening with cross pieces such as those illustrated in figure 2A. In an alternate embodiment, the opening in the cover can be comprised of a multiplicity of smaller openings in the cover, as depicted in Fig. 2B. A locking means is located on the inner disc which engages the pin 50 and holds the filter retainer in place.

A preferred locking means is comprised of a sliding plate 60 which is movably attached to the inner disc 34 of the filter retainer disc 32 with a hinge pin 62 extending from the inner disc 34 of the filter retainer disc 32, so that the sliding plate 60 rotates about the center of the hinge pin 62 while remaining in contact with the inner disc. The sliding plate 60 has an arc-shaped pin slot 64 having an effective radius equal to the distance from the hinge pin 62 to the hole in the center of the inner disc 42, whereby the center of the hole in the inner disc maintains alignment with the center of the arc-shaped slot throughout the rotation of the sliding plate.

The retainer pin 50 is comprised of a cylindrical body 52 having opposite ends and an outside diameter essentially equal to the inside diameter of the hole 42 in the filter retainer disc, a cylindrical neck 54 having a diameter smaller than the diameter of the body and equal to the width of the arc shaped slot 64, and a cylindrical head 56 having a top and a bottom and having a diameter larger than the pin neck 54, preferably equal to the diameter of the pin body 52. One end of the pin body 52 is attached to the cover 16 by conventional means, such as, a rivet 58, a screw, a thread, or a spot weld. Pin neck 54 is attached to the end of the pin body 52 opposite the attachment to the cover. The bottom of the pin head is attached to the pin neck at the end opposite the pin neck's attachment to the pin body. The retainer pin can be made of separate

elements attached by conventional means or preferably manufactured from a single piece of stock. The length of the pin body is essentially equal to the distance from the top surface of the cover to the top surface of the inner disc. The length of the pin neck is at least equal to the thickness of the sliding plate. The combined length of the pin body and pin neck is such that the bottom of the pin head is slightly lower than the top surface of the sliding plate 60 so that when the arc-shaped pin slot 64 engages the pin neck 54, the filter retainer disc 32 will be forced toward the cover, compressing the gaskets 46, 48, and creating a seal between the filter retainer 30 and the cover 16. The top of the pin head 56 can have a taper to facilitate the insertion of the retainer pin 50 through the hole in the filter retainer disc 42 and arc-shaped slot in the sliding plate 64.

The arc shaped slot 64 has a width essentially equal to the outside diameter of the pin neck and a length at least twice as long as the outside diameter of the pin head. At one end of the arc-shaped slot 64, the width of the slot is increased to allow the pin head to pass through the arc-shaped slot.

A filter is attached to the cover with the filter retainer by placing a filter 20 over the hole 18 in the cover 16, the sliding plate 60 is positioned so that the end of the arc-shaped slot 64 having an increased width is aligned with the hole in the inner disc 42, the filter retainer 30 is then placed over the opening in the cover 16 so that the retainer pin 50 passes through the hole in the inner disc 42 and the enlarged end of the arc-shaped slot 64, and the sliding plate 60 is then rotated so that the arc-shaped slot 64 engages the pin neck 54, thereby preventing the pin from passing back through the arc-shaped slot and thus attaching the filter retainer to the cover.

The filter retainer 30 has a means for limiting the rotation of the sliding plate 60 and facilitating the positioning of the sliding plate in an "open" position, where the enlarged end of the arc-shaped slot 64 lines up with the hole in the inner disc 42, and a

“locked” position, where the opposite end of the arc-shaped slot lines up with the hole in the inner disc. One embodiment of a limiting means incorporates an arc-shaped limiting slot 66 on the sliding plate 60. The arc of the limiting slot 66 is parallel to the arc of the arc-shaped slot 64 and has an effective radius larger than the radius of the arc-shaped slot 64. A locating pin 68 is attached to, and extends from, the inner disc 34 such that it engages one end of the limiting slot 66 when the sliding plate 60 is in the locked position and engages the opposite end of the arc-shaped slot when the sliding plate is in the unlocked position. The locating pin 68 is preferably hemispherical-shaped to facilitate the movement of the sliding plate 60 over the locating pin 68. A hemispherical locating pin 68 can be made, for example, by inserting and attaching a ball bearing in a hole in the inner disc 34. The width of the limiting slot 66 is slightly less than the diameter of the locating pin 68. The width of the limiting slot 66 at each of the two, opposite ends, is enlarged slightly, forming two holes each having a diameter slightly larger than the diameter of the locating pin 68. Consequently, the sliding plate 60 is held in the locked and open positions when the locating pin 68 engages each of the holes in the ends of the limiting slot 66, requiring the application of an external force to move the sliding plate between the two positions.

The sliding plate 60 preferably has a handle 70 to facilitate moving the plate between the open and closed positions. The handle 70 preferably extends parallel to the plane of the sliding plate. The handle 70 can be attached to the sliding plate or manufactured with the sliding plate as a single piece.

As described above, the sterilization container has a filter retainer mechanism. Alternative embodiments comprise having the filter manufactured as an integral part of the container as depicted in Fig. 4A, or having the filter incorporated into a self-contained removable filter unit or cartridge as depicted in Fig. 4B.



A further alternative embodiment comprises a D-ring attached to the end of pin 50 connected to the cover 16. In this embodiment, the filter and filter retainer are mounted on the inside of the sterilization container. This arrangement permits the external D-ring to be used as a handle to lift the cover without coming into contact with the side edges of the cover 16, thereby reducing the risk of contamination of the container contents.

While the foregoing embodiment works sufficiently well in a flash sterilization environment, it has been found that improvements to the basic structure of the invention are desirable if used with gas plasma. Gas plasma as a sterilization medium is fairly new and is available from, among others, Advanced Sterilization Products, a division of Johnson & Johnson, under the trademark STERRAD[®]. Gas plasma has certain advantages over the prior art. For example, ethylene oxide has been banned thereby making it more difficult to find suitable alternatives. In addition, steam sterilization cannot be used with a number of modern tools, such as cannulas, lumens, scopes, fiber optic cables, and cameras, without damaging them. While gas plasma clearly has certain distinct advantages, it has been found that it does not operate suitably well with all types of containers that were suitable for use with steam sterilization. Part of the problem is that the gas plasma does not circulate as aggressively as steam inside the container, and does not reach areas such as the corners, thereby leaving the potential for unsterilized surgical instruments or the like. Steam sterilization avoids the absorption problem by having a super-saturated environment of water molecules. The present invention, however, has provided a way for making gas plasma acceptable for use in sterilization containers, especially those in the mid-size range. For the purposes of this disclosure, mid-size is defined as approximately 15 – 18 inches in length, 9 – 12 inches in width and 2 – 10 inches in depth. The container,

especially in the mid-size container, has several advantages, including but not limited to, the following: 1) it cuts the exposure time in gas plasma sterilization; 2) it improves the effectiveness of gas plasma sterilization; and 3) it is more efficacious for gravity displacement applications.

5 A first alternative embodiment **100** of the improved gas plasma sterilization container apparatus is illustrated in the exploded view of Fig. 5A. The container **100** includes a top or lid **102** that sits on top of a bottom or pan **104**. Bottom **104** includes four sidewalls **106** and a bottom or base **108**. A pair of wire handles or bales **110** are located on opposite ends of the bottom portion **104** and are held in place by a pair of
10 lockable latches **112**.

The anodized surfaces on the lid **102** and pan **104** form an electrical insulation barrier between the two parts **102**, **104**. Gas plasma is generally electrically charged and the lid **102** and the pan **104** appear to form, in their insulated assembly, a unique construction which appears to aid the gas plasma sterilization process within container
15 **100**. The thinness of the anodized coating, i.e., less than 0.5 mils (0.0005 inches), further appears to improve the sterilization process with ultimate results appearing to be achieved when the anodized coating is in the range of 0.2 mils (0.0002 inches) to 0.3 mils (0.0003 inches). In particular, great results in achieving sterilization are achieved when the lid **102** and the bottom **104** are made out of 6061 T-6 aluminum.

20 A first set of vent holes **114** is located in top **102**. The vent holes **114** are preferably arranged as a group of four concentric circles with holes **114a**, **114b**, **114c** and **114d** in each, respectively. In all, the total number of holes may range from 100 to 500 and have a size that ranges in diameter from, but not limited to, 3/16 inches to 5/16 inches. The first set of vent holes **114** is located on the central axis **122** of the short
25 dimension of the lid **102**. The first set of vent holes **114** allows the sterilizing medium



162 to pass into the container. A pull ring 130, attached to a base 142 sits in the middle of the first set of vent holes 114 and is connected there by rivet assembly 144a, 144b, and 144c as shown in exploded detail in Fig. 5D. The lid 102 also includes four recessed dimples 136 which are adapted to engage with complimentary dimples or projections in the base 108 (not shown) so that the containers 100 can be stacked on each other and permit circulation of gas plasma therethrough at the same time.

A second set of vent holes 116 and a third set of vent holes 118 are located in the base 108 on symmetrical opposite sides of center line 120 which represents the minor axis of the base 108. The second set of vent holes 116 also comprises four concentric circles having holes 116a, 116b, 116c and 116d of the same dimensions with regard to the first set of vent holes 114. A hold-down stud 132 is located in the center of the concentric circles and is intended to make a snap fit with the retainer plate for the hydrophobic filter that goes therebetween. Similarly, the third set of vent holes 118 comprises four sets of concentric circles having holes 118a, 118b, 118c and 118d therein. A central post or stud 134 is also located in the middle thereof and adapted to snap into and engage a hydrophobic filter retainer plate in the manner previously described with regard to the flash sterilization embodiment. Associated with the first set of vent holes 114 is a circular hydrophobic filter disk 124, a hold down ring 126 and a perforated filter retainer plate 128. A central hole 156 in the retainer plate 128 snaps into and engages a stud 146 in the container as illustrated in Fig. 5E. A similar set of hydrophobic filters, rings, and retainer plates is associated with the second and third set of vent holes 116 and 118 as illustrated in Fig. 5F. Hydrophobic filters 124 should be utilized when gas plasma acts as the sterilizing medium. The TYVEK®, a trademark of E.I. du Pont de Nemours & Company, brand of polyethylene/polypropylene spun fiber is acceptable, as is Kimguard®, a trademark of the Kimberly-Clark Corporation. The

alternative embodiments **100 and 200** also work best with hydrophobic filters such as described above. In addition, hydrophobic filters do not absorb water, which allows for a quicker drying time. The concentric holes **128a, 128b, 128c, 128d and 128e**, are preferably offset from the holes **114a, 114b, 114c, and 114d** so as to prevent "striethrough". That is to prevent sharp objects from entering the holes **114a, 114b, 114c and 114d** and exiting through **128a, 128b, 128c, 128d or 128e**. As illustrated in Fig. 5C the top or lid **102** includes a groove **138** which retains a gasket **140** which sits on top of the upper lip **150** of the bottom or base pan **104** as shown in Fig. 5F. Fig. 5F also shows in further detail how the bottom perforated retainer plate **152** attaches to the bottom stud **132** and keeps a hydrophobic filter in place above the second set of vent holes **116**. Similarly, Fig. 5F also illustrates how another perforated filter retainer plate **154** engages snap on stud **134** to hold another hydrophobic filter in place above the third set of perforated vent holes **118**.

The structure just described works especially well with gravity displacement or gas plasma. The gas plasma enters through the vent holes **114**, passes through the hydrophobic filter **124** and emerges through the perforated base plate **128**. Because the top vent holes **114** are not located directly above the bottom pair of vent holes **116** and **118**, the gas plasma is forced to migrate, and become somewhat turbulent as it attempts to find an exit through the second and third set of circular vent holes **116** and **118**, respectively. This forces the gas plasma to more thoroughly mix and contact medical instruments or the like inside of the container **100** and also forces it further towards the corners and edges of the container. As a consequence, the invention described is one of a few containers, if any, that has been approved by major manufacturers for use with gas plasma. It is believed that no other sealed container in the mid-size range for sterilization of blades and cannulas has been approved at the present time. The present

invention in the mid-size range with the offset sets of vent holes works in all methods of sterilization, including flash sterilization and gas plasma sterilization.

A second alternative embodiment **200** of the gas plasma version is illustrated in an exploded view shown in Fig. 6A. The base, or bottom pan **104** of the embodiment **200** is identical in all respects to the base **104** illustrated in Fig. 5A and associated with the first gas plasma alternative embodiment **100**. Namely, the base **104** also includes a pair of offset circular vent holes **116** and **118** each having a hydrophobic filter and a retainer plate associated therewith as seen, for example, in detail in Fig. 5F. The difference between embodiment **100** and **200** is that alternative embodiment **200** includes a pair of circular sets of vent holes **202** and **204** arranged symmetrically on opposite sides of the small dimension center line **226**. The structure of the first and second set of vent holes **202** and **204** is identical to the structure of the set of vent holes **114** in the lid **102** of embodiment **100** as illustrated in Figs. 5A – 5F. Namely, the first set of vent holes **202** comprises four concentric circles of vent holes **202a**, **202b**, **202c** and **202d**. A pull ring **218** connected to a base **220** is located in the center of the concentric circles **202**. Pull ring **218** is attached to the base by a rivet assembly **244a**, **244b**, and **244c** as illustrated in exploded detail view in Fig. 6D. Similarly, the second set of vent holes **204** comprises four concentric circles having vent holes **204a**, **204b**, **204c** and **204d** arranged around a pull ring **222** attached to a base **224** and connected to the lid **226** in the same manner as illustrated in Fig. 6D. The first set of vent holes **202** has associated with it a hydrophobic filter disk **206**, a ring **208**, and a perforated retainer plate **210** that snaps and attaches to a post on the bottom side of the base plate **220** in the same manner that the post **146** of the embodiment **100** engages its perforated retainer plate **128** as illustrated in Fig. 5E. Similarly, another hydrophobic filter disk **212** is located under the second set of vent holes **204**, and has an associated ring **214**

and perforated retainer plate 216 below it which also engages with a snap on post associated with pull ring 222 and base plate 224. This second alternative embodiment 200 also provides for improved circulation of the gas plasma through the container so as to contact all the surgical instruments and the corners of the device.

5 The present invention can be utilized for "stat" sterilization, for example, where immediate sterilization is required because an instrument becomes contaminated during surgery. Experimentation has shown that in order to reduce sterilization time, the amount, i.e., mass, of material to be sterilized must be limited. Limiting the amount of material to be sterilized can be accomplished by weighing the instruments. Weighing
10 of instruments, however, is time consuming, difficult, and unreliable because the instruments are of varying masses and have odd surface areas. An improved method according to the present invention is to limit the amount of material for "stat" sterilization by utilizing a basket 80, as shown in Fig. 7A, which limits the amount of items sterilized by limiting the space in which instruments could be placed. This, in
15 turn, limits the total mass of the instruments and guarantees that they can be sterilized sufficiently in a short period of time. Experimentation has shown that baskets which limit the volume of instruments to be sterilized to no more than twenty percent (20%) of the volume of the sterilization container allow for the most effective "stat" sterilization. In these experiments, a basket approximately 12 inches long, by 6 inches
20 wide and 2 inches high, or a volume of approximately of 149 cubic inches, was utilized to determine the effectiveness of limiting the mass of instruments to be sterilized on a "stat" basis. The most effective use of the basket occurred in a sterilization container 18.1 inches long, by 11 inches wide and 4 inches high, or a volume of approximately 796 cubic inches.

The basket 80 of the preferred embodiment of the volume limiting present invention consists of a base 82, and two side walls 84 attached to the base 82. The base 82 and the side walls 84 are highly perforated 83. The basket 80 also contains two handle fixtures 86 on opposite sides. The handle fixtures 86 contain feet 88 extending past the base 82, and a handle portion 85 that extends beyond the side walls 84. The feet 88 and handle extend 85 beyond the sidewalls 84 so that only one basket 80 could be placed in the container.

The basket 80 may also utilize a divider system 90 to limit the amount of instruments placed in the basket 80. The divider system 90 consists of a series of brackets 92 which could be scalloped to prevent instruments from being tightly packed.

In summary, the gas plasma embodiments make it possible to convert a flash sterilization container such as illustrated in Figs. 1A through 4B into a version which is imminently acceptable and suitable for use with mid-size sterilization containers. Not only does it work with mid-size containers, it also permits sterilization to take place in approximately half the time and works especially well in a gravity displacement environment. Moreover, delicate instruments, such as cameras which cannot be sterilized with steam or ethylene oxide, can be effectively sterilized.

It is believed that by making the base and lid of the container out of aluminum and anodizing the aluminum to a thickness of 0.5 mils (0.0005 inches) or less that improved sterilization results are achieved in a gas plasma sterilization medium. These results, it is believed, allowed sterilization containers that are so constructed to pass strict approval requirements. It is further believed that by maintaining the anodized coating in the 0.2 mils (0.0002 inches) to 0.3 mils (0.0003 inches) range, optimum sterilization results are achieved. The use of 6061 T-6 aluminum is further believed to add to these improved sterilization results. It is additionally believed that by

electrically insulating the top of the container from the bottom of the container improves sterilization results with a gas plasma sterilization medium occur. This electrical insulation can be achieved by anodizing the mating parts (top and bottom) of the container as indicated and preventing other paths of electrical current from flowing between the two container parts, e.g., clamps holding the two parts together without appropriate electrical insulation.

While the invention has been described with reference to the preferred embodiment, it will be appreciated by those of ordinary skill in the art that modifications can be made to the structure and form of the invention without departing from the spirit and scope thereof.

WE CLAIM:

1. A metal sterilization container (100, 200) used for sterilizing instruments placed therein and surrounded by a gas plasma sterilizing medium, said container (100, 200) comprising:

an aluminum lid (102, 226) having a first set of vent holes (114, 202 and 204) therein;

an aluminum bottom (104) attachable to said lid (102, 226), said bottom (104) having sidewalls (106) and a base (108);

a second set of vent holes (116) located in said base (108) of said bottom (104);

a filter medium (124, 206, 212), permeable to the flow of gas plasma but inhibiting dust and other airborne particles and microorganisms, associated with each of said sets of vent holes (114, 116, 202 and 204); and

an oxide film covering said aluminum lid (102, 226) and said aluminum bottom (104) of a thickness not exceeding 0.5 mils (0.0005 inches); and

wherein the gas plasma sterilizing medium passes through said first set of vent holes (114, 202 and 204) and filter medium, around the inside of said container (100, 200) and passes through said second (116) set of vent holes and filter medium.

2. The container of claim 1 wherein said oxide film covering is of a thickness of from 0.2 mils (0.0002 inches) to 0.3 mils (0.0003 inches)..

3. The container of claim 2 wherein the aluminum is 6061 T-6.

4. The container of claim 1 further comprising a third set of vent holds (118) located in said base (108) of said bottom (104).

5. The container of claim 4 wherein said first set of vent holes (114, 202 and 204) and said second (116) and said third (118) set of vent holes are offset in a predetermined direction relative to each other whereby the gas plasma sterilizing medium may pass through said first set of vent holes (114, 202 and 204) through said

container (100, 200) and be forced to move in a direction different than said predetermined direction to pass through said second (116) and said third (118) set of vent holes thereby creating a turbulent flow of said gas plasma within said container (100, 200).

5 6. The container of claim 5 wherein said oxide film covering is of a thickness no less than 0.2 mils (0.0002 inches).

 7. The container of claim 6 wherein said oxide film covering is of a thickness no greater than 0.3 mils (0.0003 inches).

 8. The container of claim 7 wherein said aluminum is 6061 T-6.

10 9. The container of claim 8 wherein said gas plasma has an electric field effect.

 10. The apparatus of claim 1 further comprising:
 a fourth set of vent holes (204) located in said lid (226), and
 wherein said lid (226) has a minor dimension center line (226) and said
15 first (202) and fourth (204) set of vent holes are located on opposite sides of said minor dimension center line (226).

 11. The apparatus of claim 1 wherein said gas plasma has an electric field effect.

 12. A system for sterilizing sterilizable items in a container with a gas
20 plasma, said system comprising:

 means for introducing a gas plasma (160, 162);

 an aluminum lid (102, 226) having a first set of vent holes (114, 202 and
25 204) located therein;

 an aluminum bottom (104) attachable to said lid (102, 226), said bottom
 (104) further including a base (108) having a center line (120) through its minor planar
 dimension;

a second (116) and third (118) set of vent holes located on opposite sides of said minor planar dimension center line (120) of said base (108); and

filter means (124, 206), permeable to the flow of gas plasma and inhibiting dust and other airborne particles and microorganisms, located adjacent to said sets (114, 202, 204, 116, 118) of vent holes,

wherein said gas plasma passes through said first set (114, 202 and 204) of vent holes and said filter means (124, 206), comes into contact with said sterilizable items, and passes through said second (116) and third (118) sets of vent holes and said filter means (124, 206).

13. The system of claim 12 wherein said metal lid (102, 226) and said metal bottom (104) are electrically insulated from one another.

14. The system of claim 13 further comprising:

a fourth set of vent holes (204) located in said lid (226), and,

wherein said lid (226) has a minor dimension center line (226) and said first (202) and fourth (204) set of vent holes are located on opposite sides of said minor dimension center line (226).

15. The system of claim 12 wherein said gas plasma has an electric field effect.

16. The system of claim 15 wherein said aluminum lid (102, 226) and said aluminum bottom (104) are electrically insulated from one another.

17. The system of claim 16 wherein said electrical insulation is formed by said oxide film covering said aluminum lid (102, 226) and said aluminum bottom (104).

18. The system according to claim 17 wherein said oxide film covering is of a thickness no less than 0.2 mils (0.0002 inches).

19. The system according to claim 18 wherein said oxide film covering is of a thickness no greater than 0.3 mils (0.0003 inches).

20. The system according to Claim 17 wherein said aluminum is 6061 T-6.

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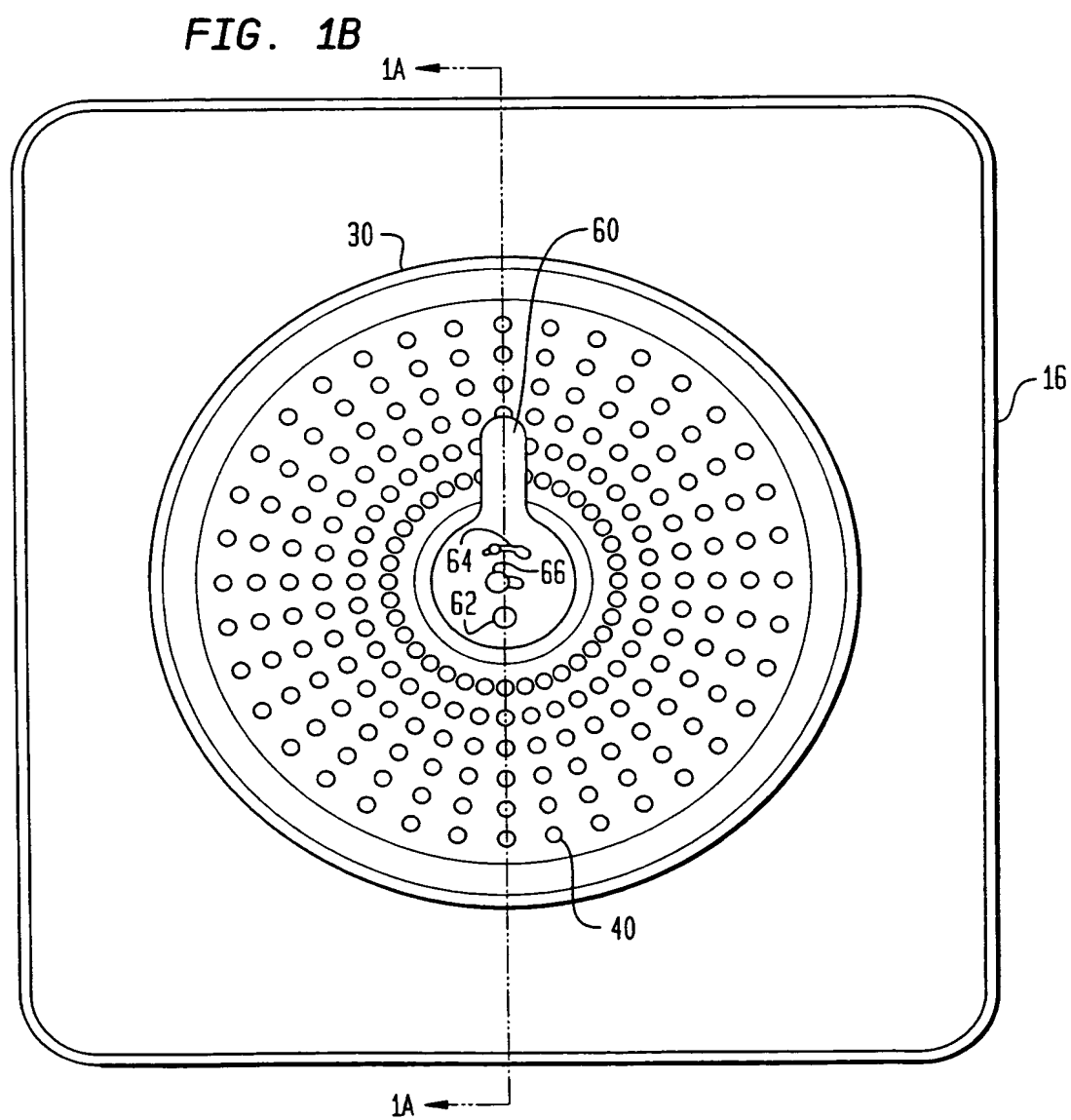
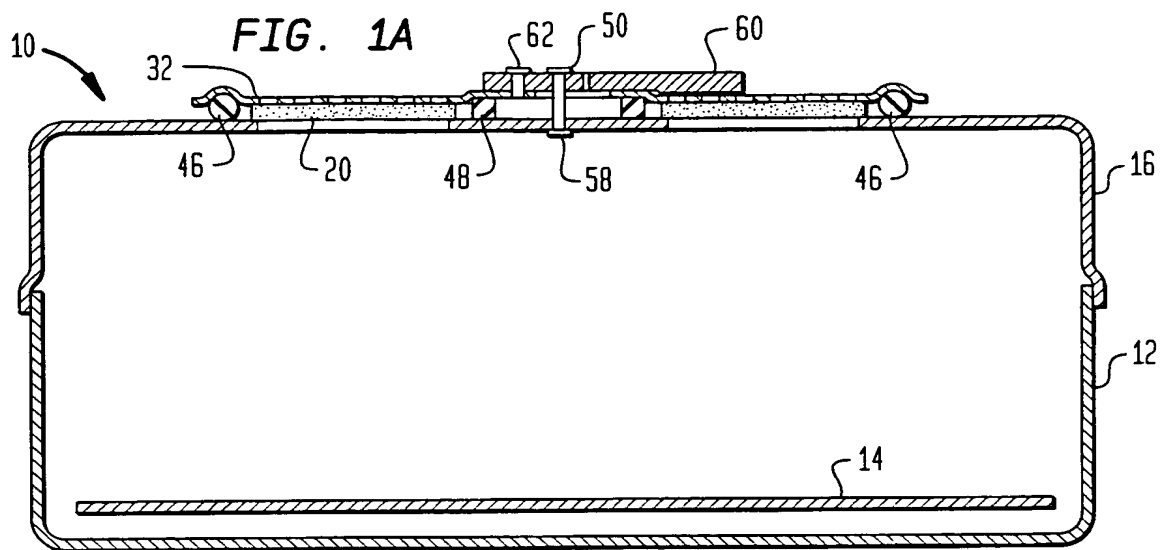
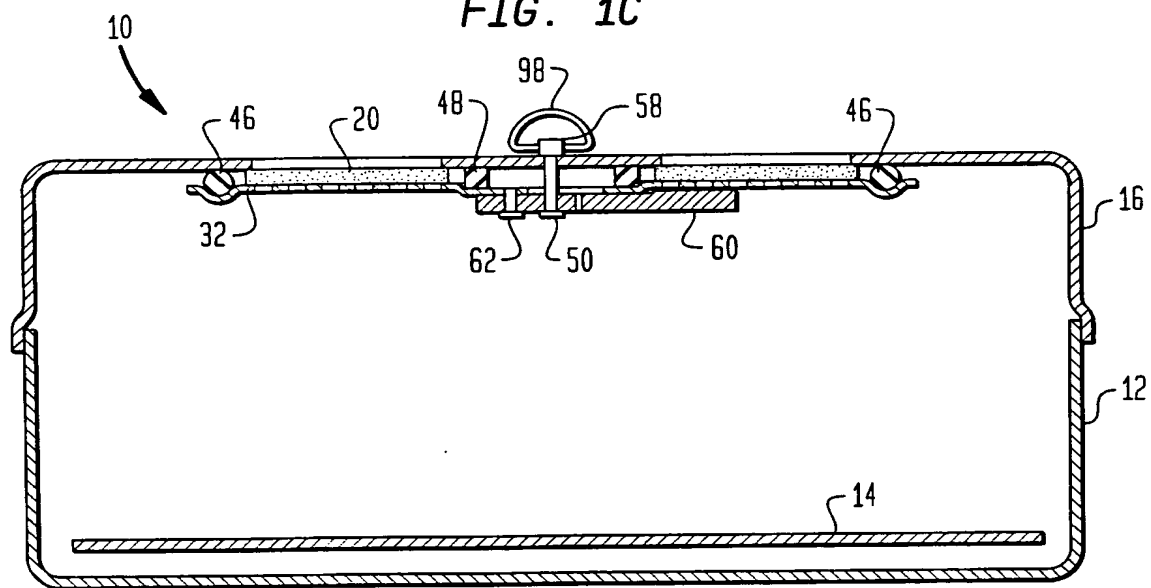
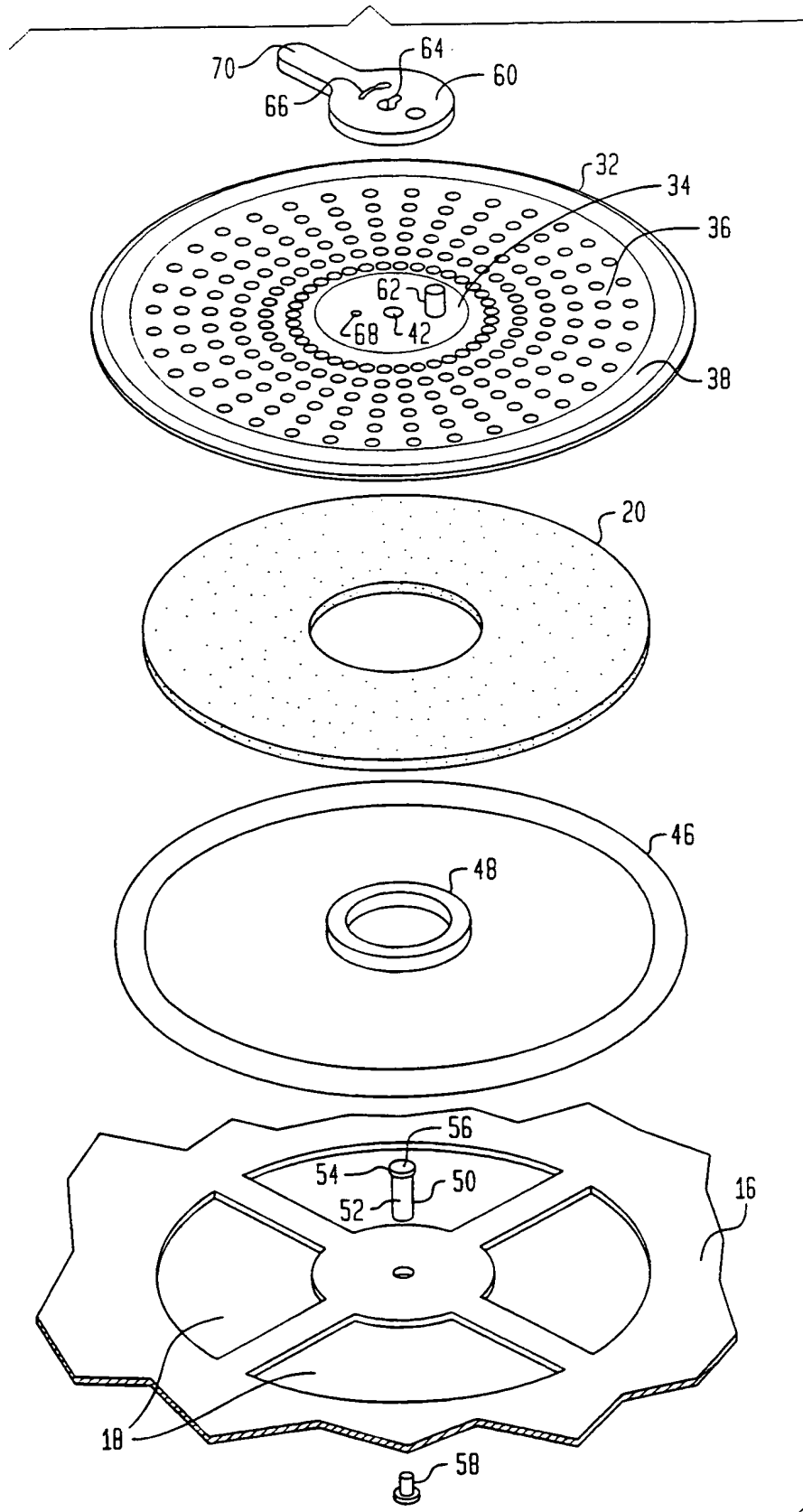




FIG. 1C



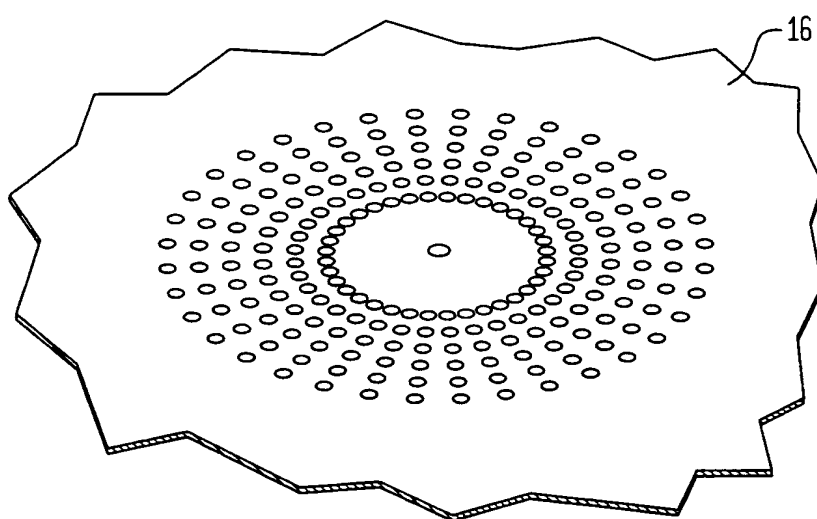
3/15
FIG. 2A





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FIG. 2B



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FIG. 3A

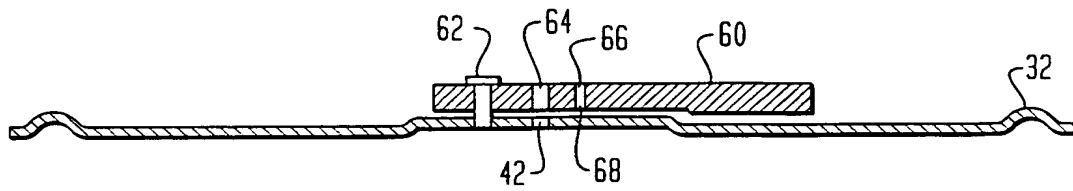


FIG. 3B

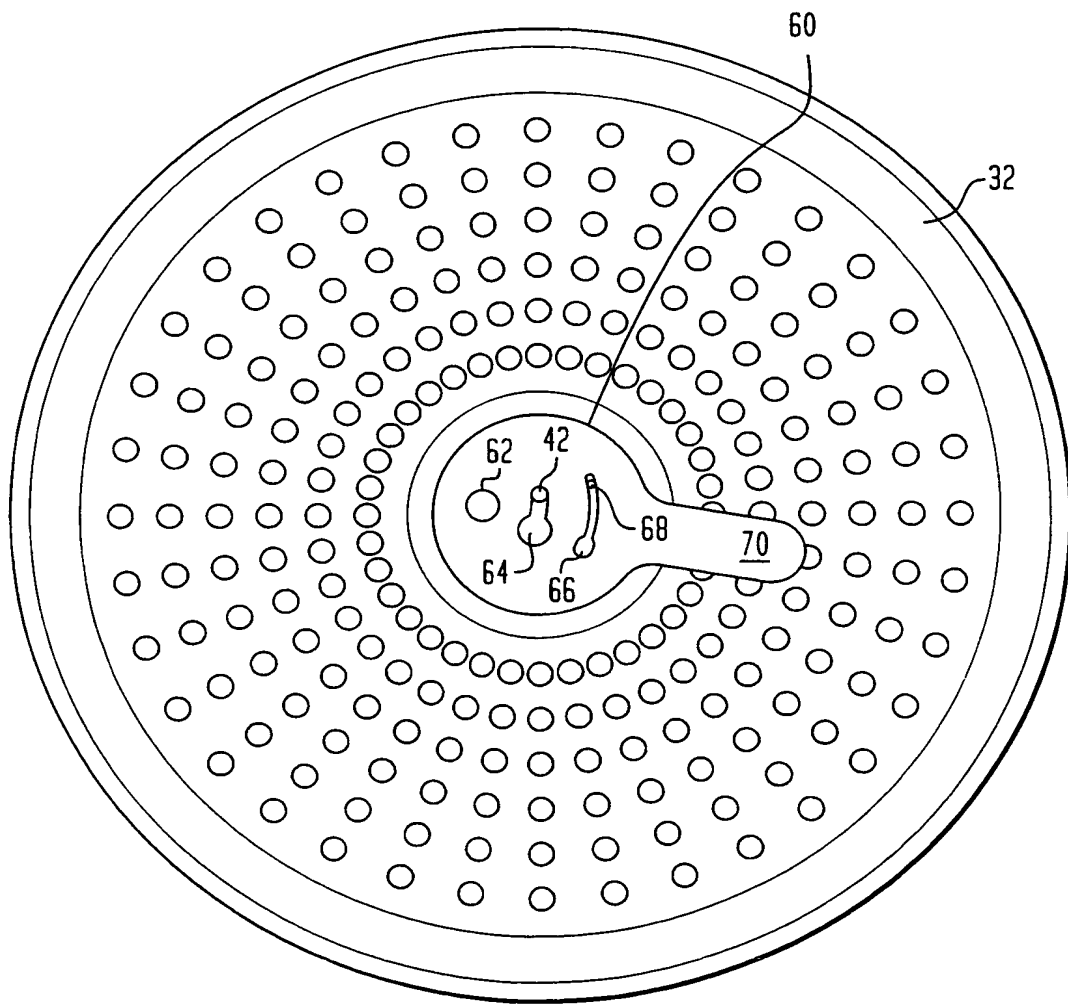
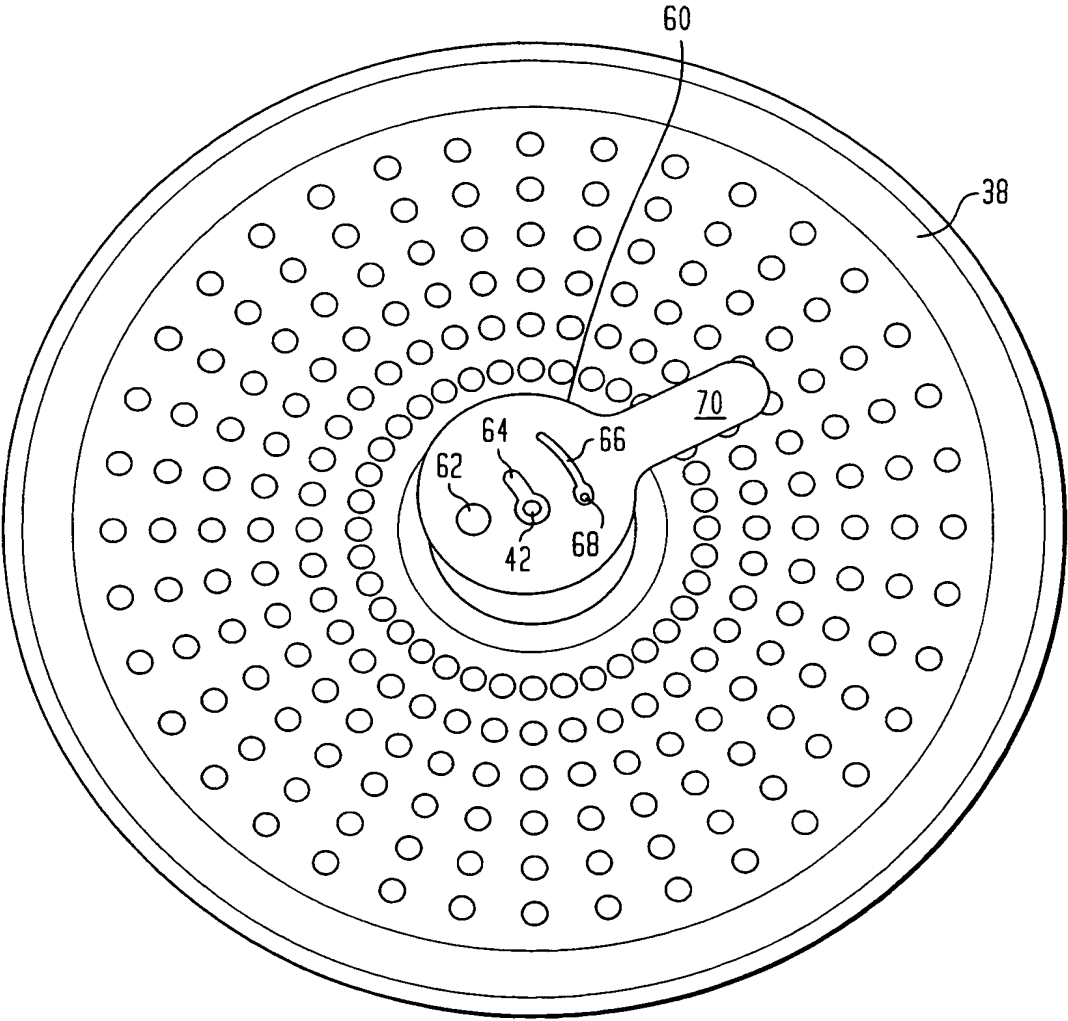


FIG. 3C



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FIG. 4A

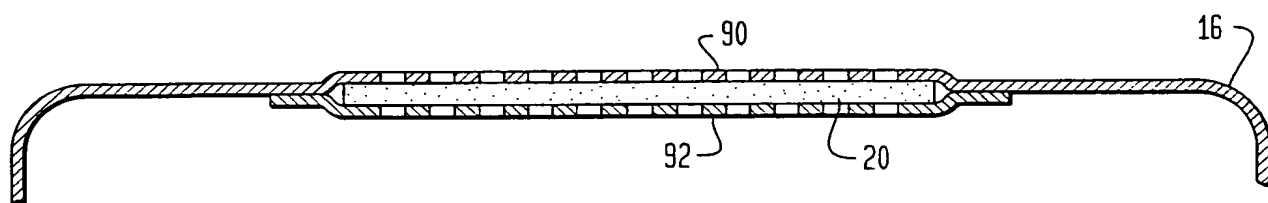


FIG. 4B

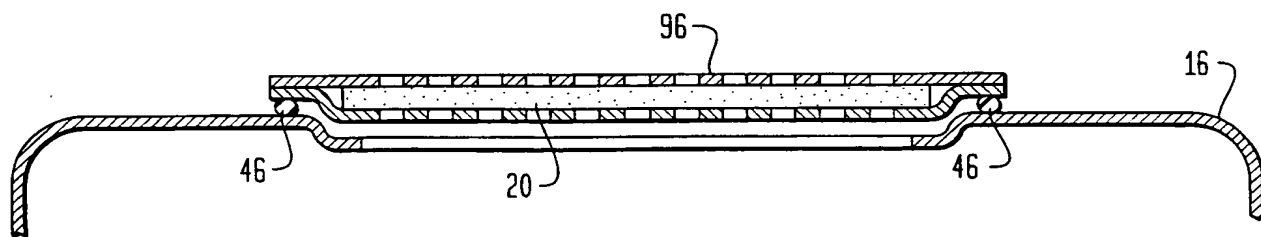
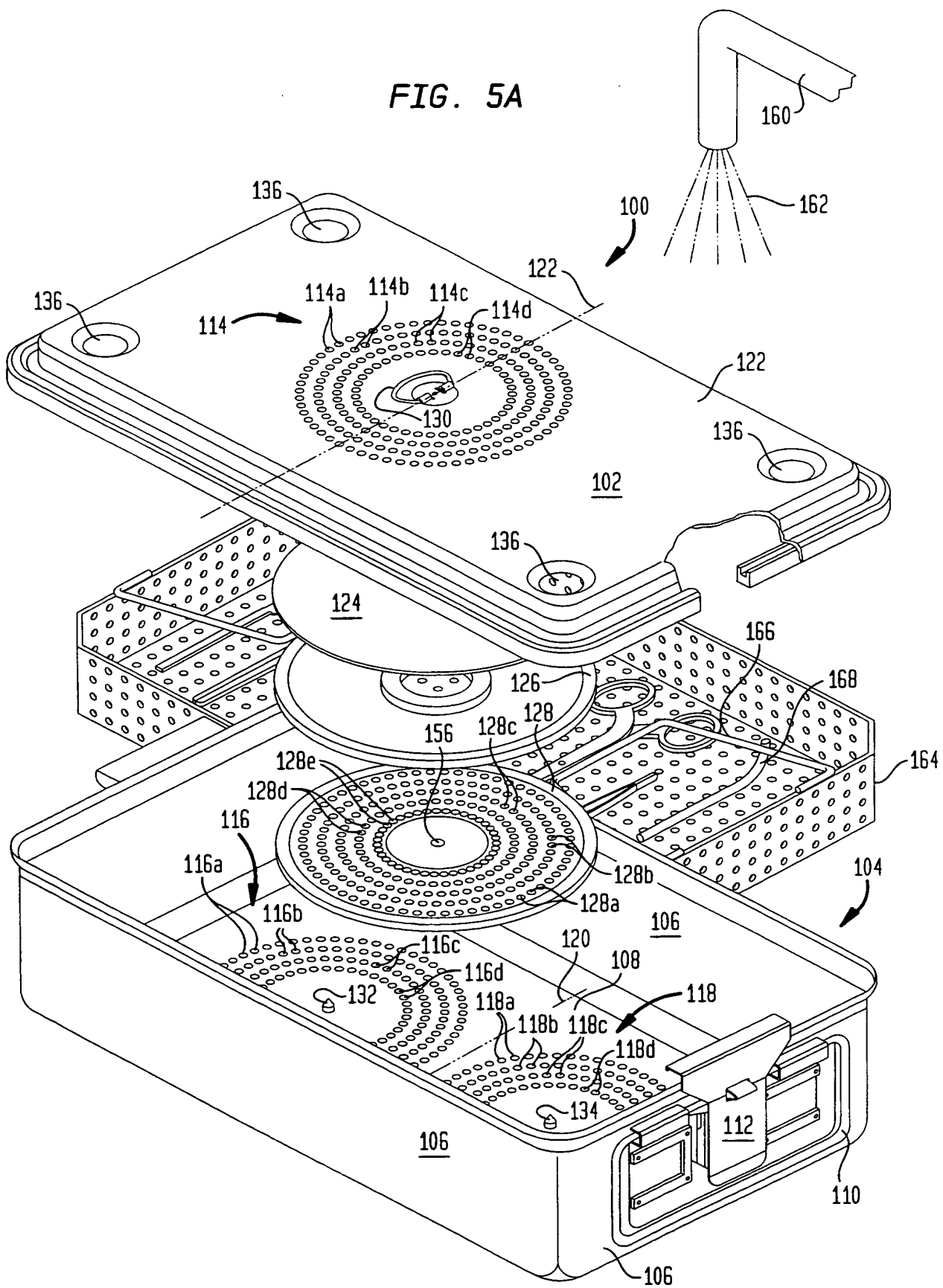


FIG. 5A





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FIG. 5B

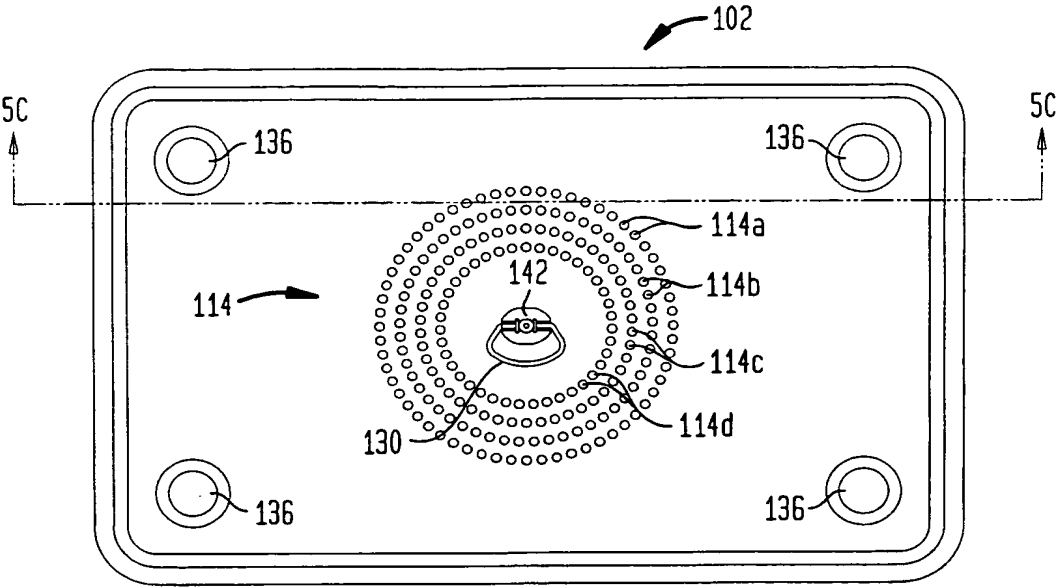


FIG. 5C

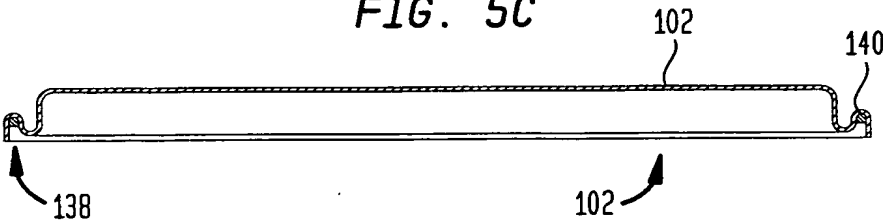


FIG. 5D

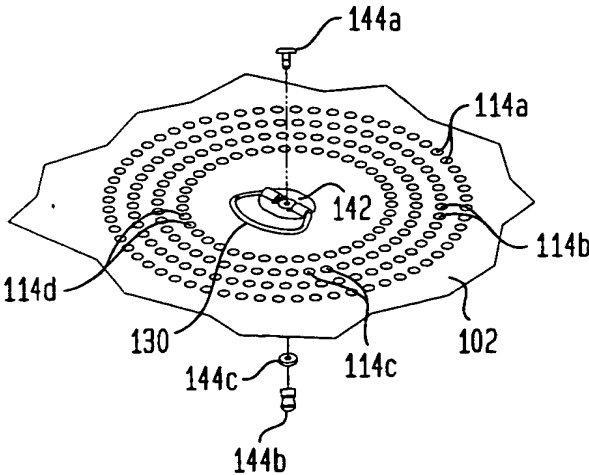


FIG. 5E

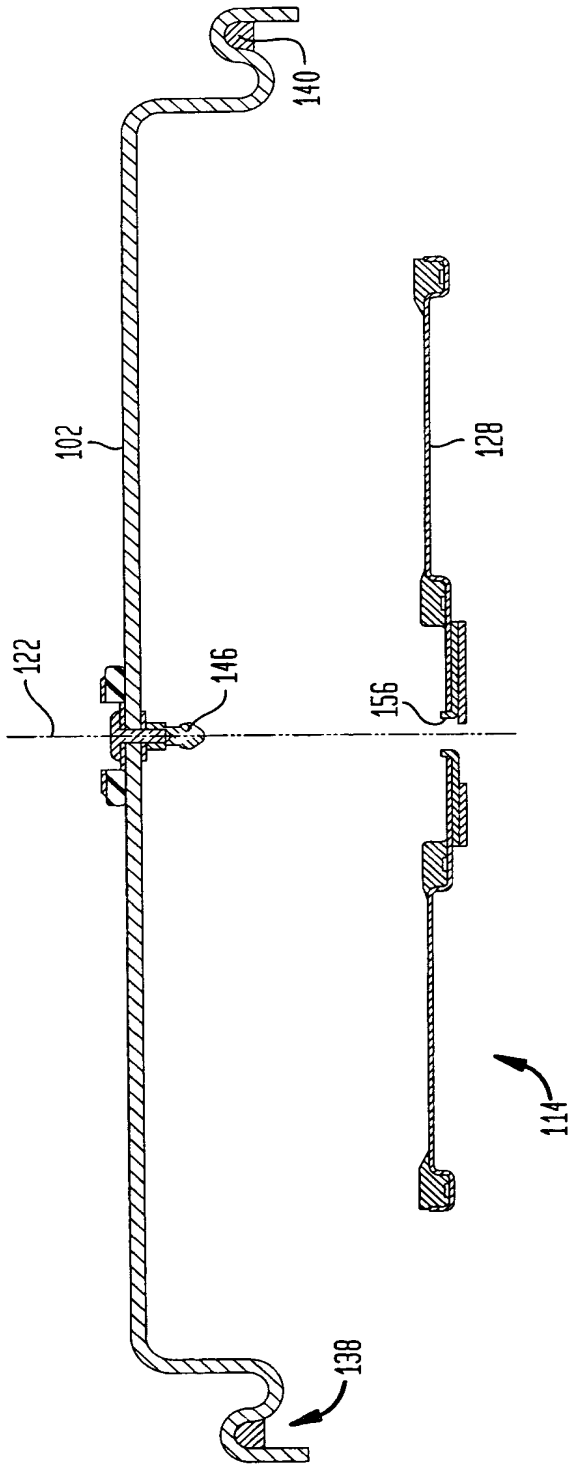
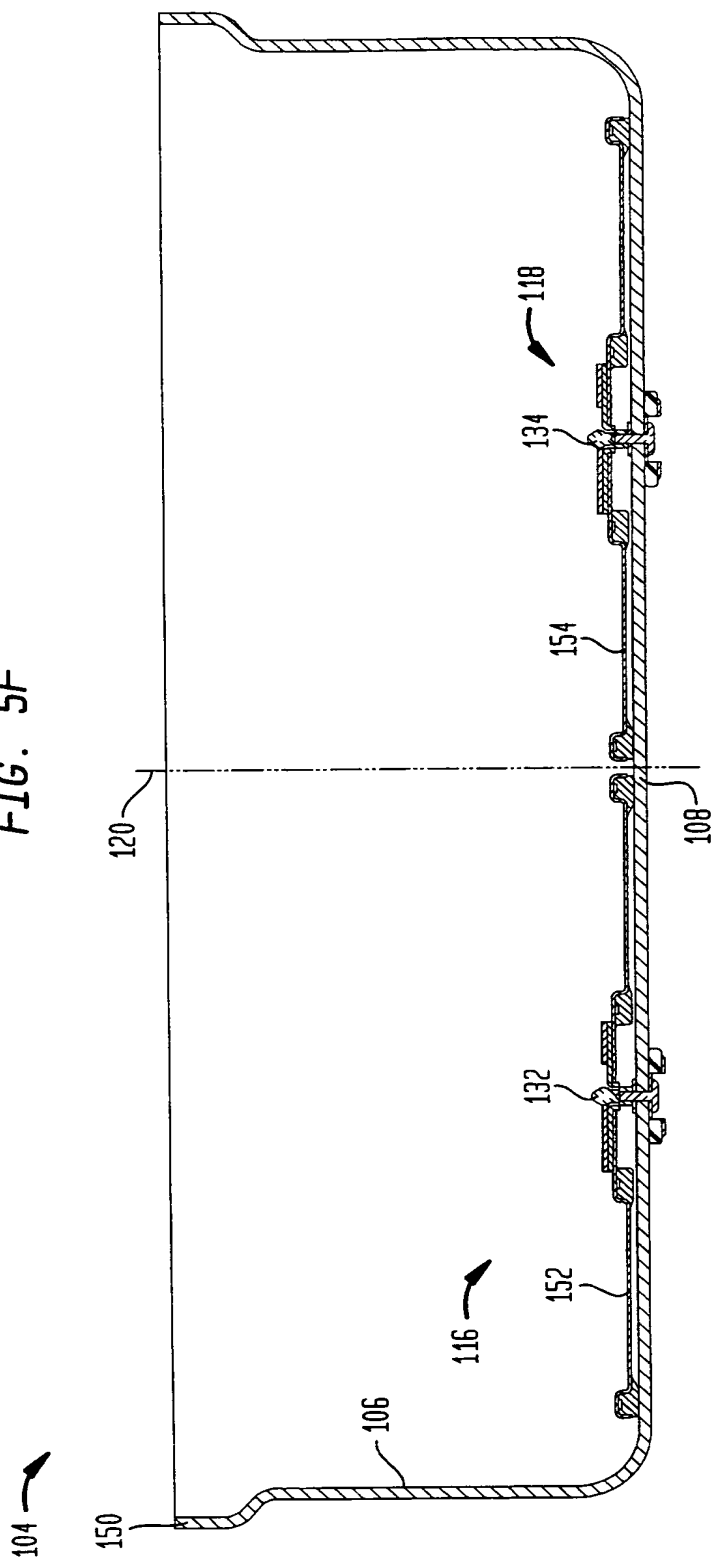


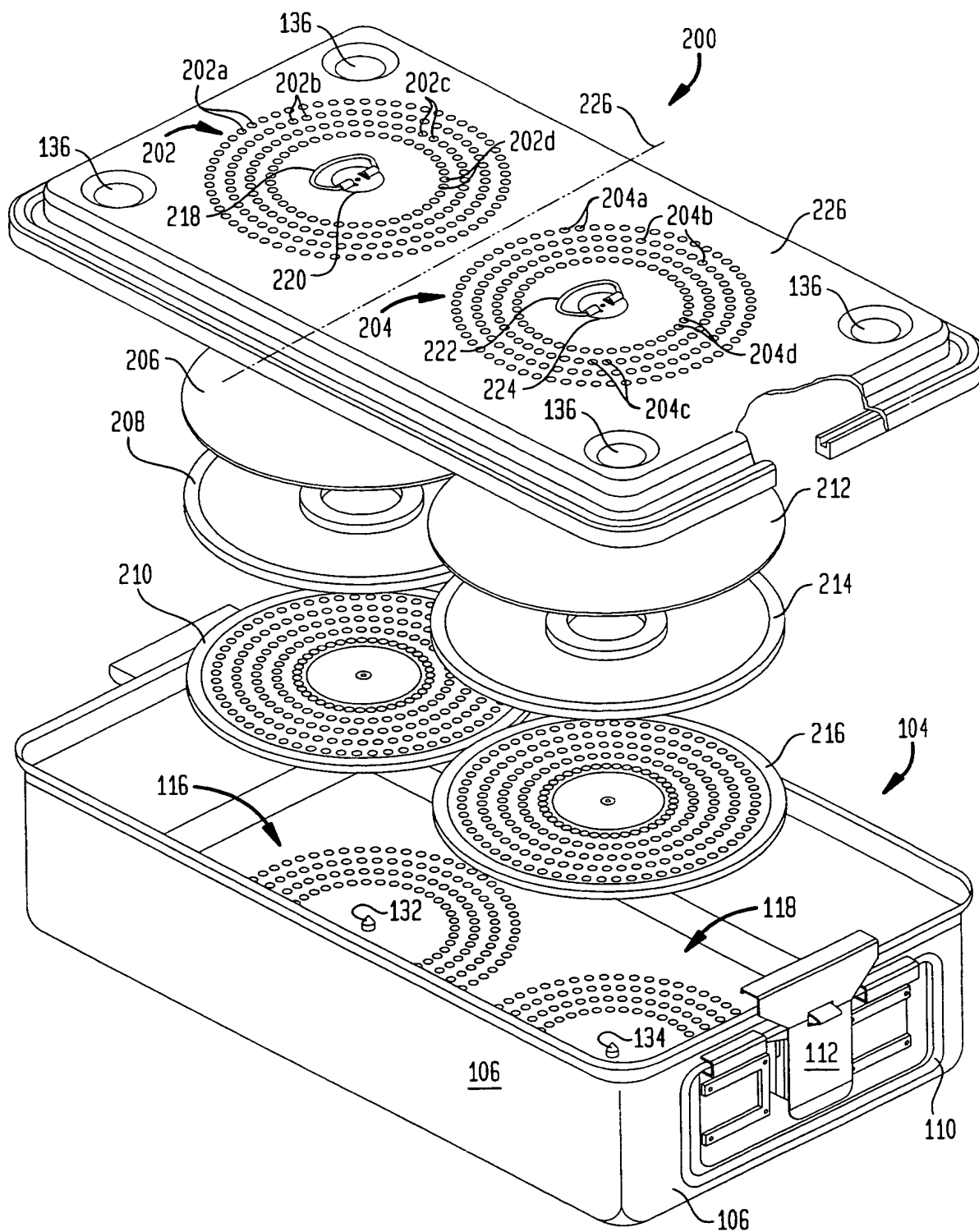
FIG. 5F





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FIG. 6A



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FIG. 6B

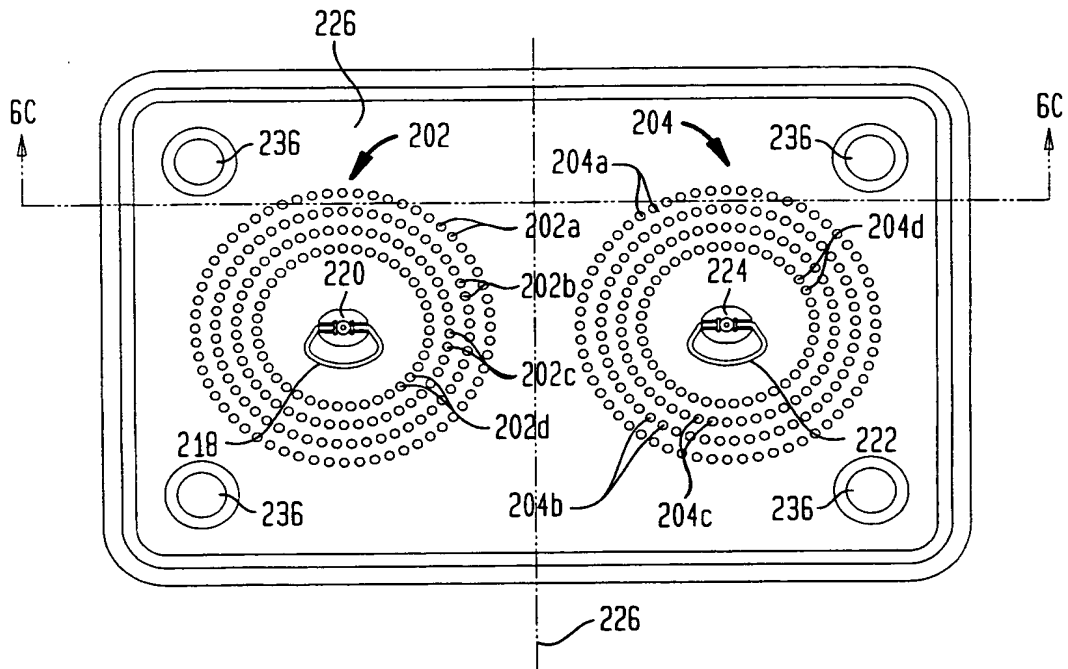


FIG. 6C

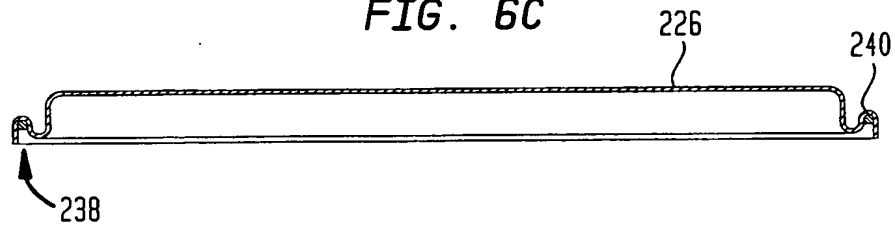


FIG. 6D

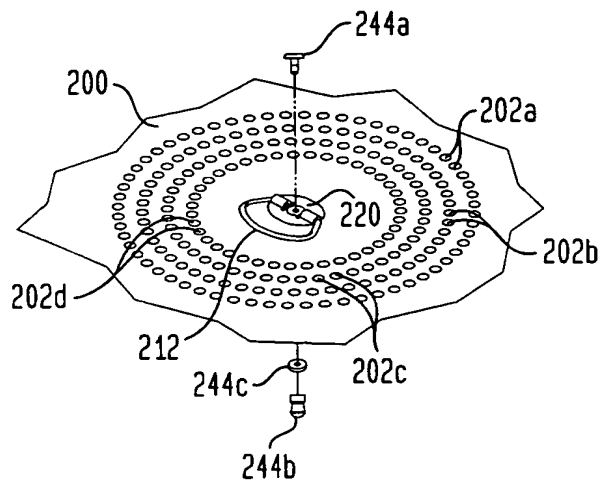
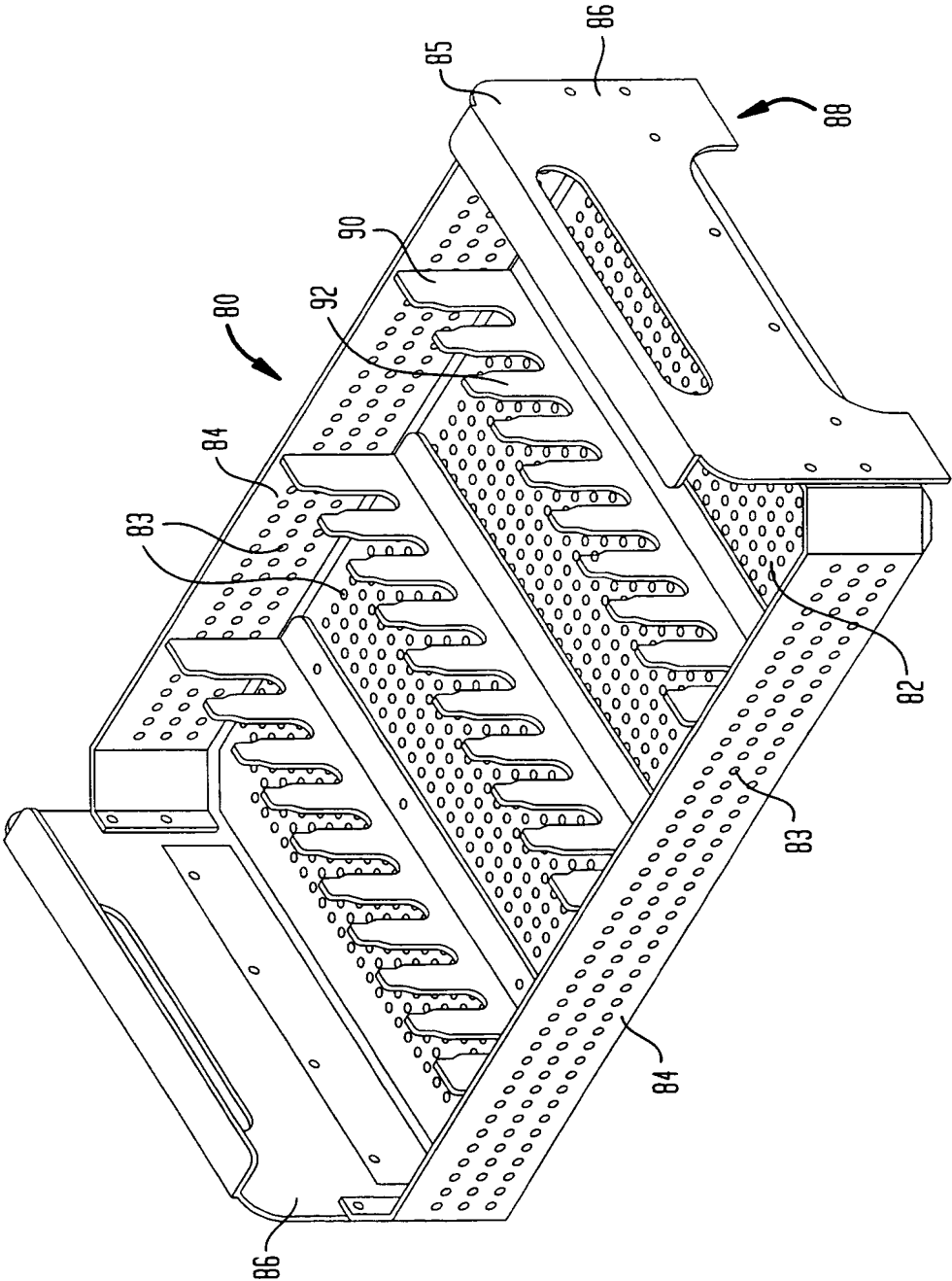




FIG. 7A



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FIG. 7B

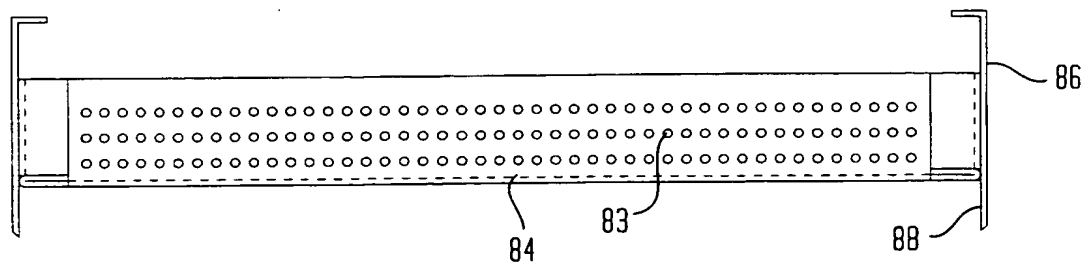


FIG. 7C

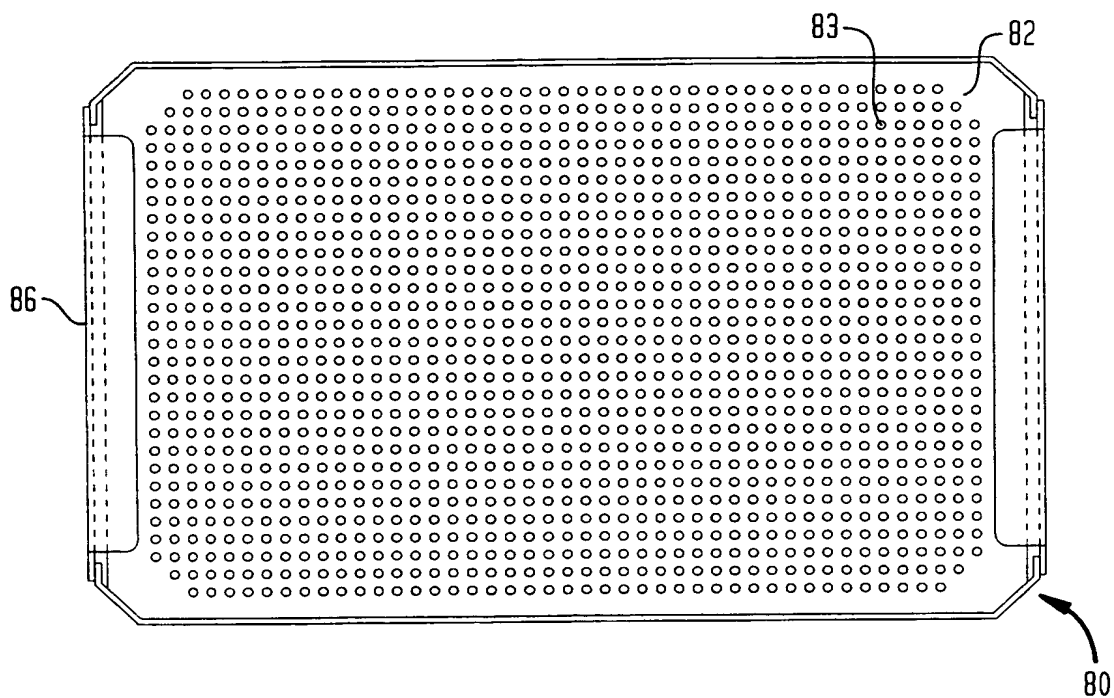
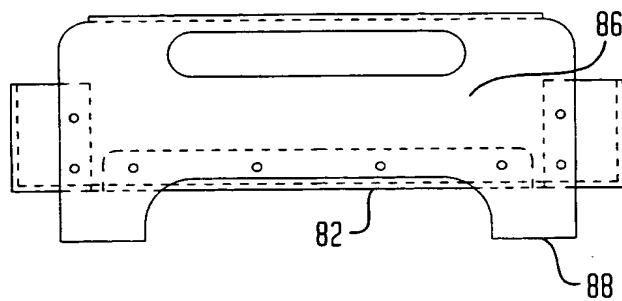


FIG. 7D





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